

**PREPARATORY SURVEY (2) REPORT
ON
THE PROJECT FOR BREAST CANCER SCREENING AND
PREVENTION CAPACITY IMPROVEMENT
IN
THE REPUBLIC OF SERBIA**

March 2010

JAPAN INTERNATIONAL COOPERATION AGENCY

FUJITA PLANNING CO., LTD.

**Ministry of Health
The Republic of Serbia**

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PREFACE

Japan International Cooperation Agency (JICA) conducted the preparatory survey (2) on the Project for Breast Cancer Screening and Prevention Capacity Improvement in the Republic of Serbia.

JICA sent to Serbia a survey team from May 27 to June 20, 2009.

The team held discussions with the officials concerned of the Government of Serbia, and conducted a field survey at the study area. After the team returned to Japan, further studies were made. Then, a mission was sent to Serbia in order to discuss a draft outline design, and as this result, the present report was finalized.

I hope that this report will contribute to the promotion of the project and to the enhancement of friendly relations between our two countries.

I wish to express my sincere appreciation to the officials concerned of the Government of the Republic of Serbia for their close cooperation extended to the teams,

March 2010

Nobuko Kayashima
Director General, Human Development Department
Japan International Cooperation Agency

Letter of Transmittal

We are pleased to submit to you the basic design study report on the Project for Breast Cancer Screening and Prevention Capacity Improvement in the Republic of Serbia.

This survey was conducted by Fujita Planning Co., Ltd., under a contract to JICA, during the period from October 2009 to March 2010. In conducting the survey, we have examined the feasibility and rationale of the project with due consideration to the present situation of Serbia and formulated the most appropriate outline design for the project under Japan's grant aid scheme.

Finally, we hope that this report will contribute to further promotion of the project.

Very truly yours,

Tamotsu Nozaki
Project manager,
Preparatory Survey team on
the Project for Breast Cancer Screening and Prevention
Capacity Improvement
Fujita Planning Co., Ltd.

Summary

Summary

1. Outline of the Country

The Republic of Serbia (hereinafter referred to as “Serbia”) is a landlocked country bordered to the north, east, south and west by Hungary, Romania and Bulgaria, Macedonia and Albania, and Croatia, Bosnia-Herzegovina and Montenegro, respectively. It occupies the western part of the Balkan Peninsula. The entire northern part of Serbia including the plain has a continental climate, with a temperature difference between summer and winter and little precipitation.

The population of Serbia is estimated at 7.5 million and it is falling at the rate of 1.97%. Although a large proportion of the population is of reproductive age, the average age of the population is expected to rise because of the shrinking population. In terms of ethnicity, Serbians account for 83 % of the population followed by Hungarians, who account for 4 %. The rest is made up of the other ethnic minorities including Magyars and Croats.

The per capita gross national income (GNI) of Serbia was US\$ 5,700 (in 2008: the World Bank: WB). According to the International Monetary Fund (IMF), the per capita gross domestic product (GDP) of Serbia was US\$ 6,782 (in 2008). Although this figure is far smaller than the GDPs of the Western European countries and slightly smaller than the corresponding figures for Romania and Bulgaria (US\$ 6,857), which are members of the European Union (EU), it is larger than those for neighboring countries, such as Macedonia and Bosnia-Herzegovina (US\$ 4,625). Agriculture, forestry and fisheries, the mining and manufacturing industries, and the service industries account for 12.3 %, 24.2 % and 63.5 % of the GDP, respectively (June 1st, 2009: the Japan Center for International Finance). Serbian country is received a harsh blow by Ethnic Conflicts and the economic sanction after 1990, and exists at on the way of a social economic rebuilding now.

2. Background of the Project

With regard to breast cancer, which has a higher incidence rate (25% of all cases of cancer in females) in Serbia, the early-stage detection rate in this country remains at 25%, and a large proportion of breast cancer patients die within three years of the onset of the disease. Cancer is the second highest cause of death (19.9%) in Serbia following cardiovascular diseases. The main reasons for this situation are the lack of a proper medical screening system and delays in early stage detection and treatment. The delay in the detection of cancer leads to the high mortality rate, and also increases the physical and economical burden on patients as well as on their families, due to the need for treatment for advanced cancer. It also increases the financial burden borne by the state due to expenditure on treatments using anti-cancer agents.

In this situation, in 2005 the Ministry of Health (hereinafter referred to as “MoH”) of Serbia established the “National Guidelines for Cancer Prevention”, and in 2007 made the

program for cancer diagnosis and treatment the top-priority issue in its “Operating Plan for Health Policies”. The activities to promote early-stage detection of breast cancer in particular are clearly mentioned in this program, together with the need to establish diagnostic techniques and to improve cancer treatment.

Against this background, the Government of Serbia requested grant aid cooperation from the Government of Japan in August 2006 for the procurement of breast cancer screening equipment (mammography units and ultrasound scanners) to be installed at 45 health and medical facilities in the country in order to establish an early-stage breast cancer detection system (a free screening system). In response to this request, the Japan International Cooperation Agency (JICA) dispatched the First Preparatory Survey (hereinafter referred to as “Preparatory Survey (1)”) team to Serbia from late May to late June 2009 in order to examine the necessity for and relevance of the requested project and to clarify the details of the facilities to be equipped, together with their condition and scale. The survey settled that the prevention of breast cancer is an important issue in the health sector of Serbia, and in February 2009 the National Assembly approved the “National Program for Prevention of Breast Cancer,” which urgently requires the establishment of a screening system including the procurement of equipment. Thus it has been confirmed that the requested project is in accordance with the above-mentioned program. It was also confirmed that a Working Group consisting of 12 experts appointed by the MoH in April 2009 (medical doctors and researchers from the MoH, the Institute of Public Health of Serbia, the Institute of Radiology and Oncology, Serbia, Tertiary Hospitals, the Health Insurance Fund, etc) has already been established for the implementation and operation of the above mentioned program, and that the training of the radiologists and radiographers needed for the implementation of the screening is to be planned and implemented accordingly.

As for the facilities to be equipped and the equipment to be supplied, around half of the facilities originally listed have been deleted from the request list since they had been equipped by the self-help efforts of the Serbian government as well as through Italian aid after the request to the Japanese government had been made. There was also a request for modification of the facility list in view of the number of people expected to have medical check-ups, and the availability of medical specialists and technical experts to be assigned within each municipality. Due to these changes, the survey team carried out its survey at a total of 44 facilities.

On the basis of the field survey results, the survey team held discussions with the counterparts and set up the following criteria for the selection of facilities to be equipped;

- 1) 1 set of mammography equipment to be supplied per 12,000 to 14,000 of population eligible for breast cancer screening (females in the age range 45 to 69 years old) in each District, and

- 2) Each facility must have already assigned a radiologist and a radiographer, and they are expected to complete the training to be implemented by the Working Group by March 2011, when the requested equipment is to be supplied. In line with these criteria, the survey team reorganized the requested items. As a result, a revised request was made for analog mammography units with mammography related equipment such as an X-ray film processor, schaukasten (hereinafter referred to as “X-ray film viewer”) and phantom for 30 facilities, digital mammography units with mammography related equipment for 2 facilities and mammography related equipment for 7 facilities (39 facilities in total).

3. Outline of the Results of the Field Survey and the Contents of the Project

After careful consideration of the outcomes of the Preparatory Survey (1) and confirmation of the need for and the relevance of this Project under the Grant Aid Cooperation Scheme, the Government of Japan made the decision to dispatch a survey team to conduct a Second Preparatory Survey (hereinafter referred to as “Preparatory Survey (2)”). In accordance with this decision, JICA dispatched the Preparatory Survey (2) team to Serbia from October 27th to November 26th, 2009. After having confirmed the contents of the request and holding discussions on the same with the MoH, which is the competent authority in Serbia for this Project, as well as the implementing agencies and the medical facilities at the 39 project sites located throughout the country, and having studied the conditions at the sites and evaluated and examined the requested equipment, the team drew up a draft outline design. The team compiled the details of the draft outline design into the draft report for the Preparatory Survey (2). The team explained the content of the report to the counterpart personnel and held discussions with them in Serbia from March 7th to March 14th, 2010. The survey team confirmed that pilot screening and publicity activities had been carried out in each district using mobile clinics since June 2009. And, it was confirmed that the number of people being screened was on the increase. Moreover, the screening activities are also providing opportunities for the transfer of technology in mammography by the radiological technologists of the Institute of Radiology and Oncology, Serbia and the Clinical Centre Nis to those working at the rural medical facilities. The team prepared this Preparatory Survey (2) Report on this Project on the basis of the outcomes of the above-mentioned surveys and discussions.

3.1 Basic Policy

This requested Japanese Assistance will support the procurement of mammography units and mammography related equipment necessary to establish the first breast cancer screening system to be attempted in Serbia. In the cancer screening system, it is important that all the women examined receive cancer-screening diagnosis impartially. In formulating the basic concept of this Project, consideration was given to securing and promoting impartiality, and a total of 39 medical facilities including public health centers (PHC/DZ) and key hospitals

in various areas, which will be the primary access facilities for the women to be examined, were selected as the target facilities for this Project. As the selection criteria for the target facilities, the following two factors were considered:

- 1 set of mammography unit to be supplied per 12,000 to 14,000 of population eligible for breast cancer screening (females in the age range 45 to 69 years old) in each District
- Each facility must have already assigned a radiologist and a radiographer, and they are expected to complete the training to be implemented by the working group of the National Program for Prevention of Breast Cancer by March 2011, when the requested equipment is to be supplied

3.2 Basic Plan

The main equipment to be provided in this Project includes mammography units (digital-type and analogue-type), CR systems, X-ray film processors and X-ray film viewers.

3.3 Soft Component (Technical Assistance) Plan

When operating the mammography unit (X-ray radiography of breasts), it is necessary to obtain high-resolution, high-contrast images of high quality with a low dose. To attain this effect, it is essential to use the radiography equipment at the performance required for mammography, to optimize the technical factors including the radiographic conditions, receiving system, developing process and removal of scattered radiation, and skill factors such as positioning and compressing the breasts, and to draw up and implement a total quality assurance program for these factors.

The member of Working Group for the National Program for Prevention of Breast Cancer, has also recognized that mammography in Serbia, especially in local medical centers, has not yet reached the appropriate level in radiographic positioning and quality of mammograms. Therefore, reinforcement of the technical ability of radiologist engineers is called for. It is very important and significant to improve the technology in quality control of mammographic images and equipment accuracy control in Serbia in order to build the foundations of the breast cancer screening system in Serbia. It is also important to support the establishment of the breast cancer screening system and continuous use of the medical equipment to be procured in the Grant Aid Project with appropriate accuracy, by making use of the soft components provided by Japanese engineers. Therefore, the Project requires the implementation of technical assistance by soft component.

4. Implementation Schedule and Project Cost Estimation

This Project will require a period of 15 months for its implementation, consisting of four months to complete the tender process, eight months for the manufacture, procurement and installation of the equipment, and three months for on-site implementation of the Soft Component after installation of the procured equipment.

5. Project Evaluation and Recommendation

The following direct outcomes are expected from the implementation of this Project (the scope of works of the Japanese and Serbian sides):

- ① It is expected that the number of breast cancer screening increases to 195,000 for two years by providing the mammography unit and mammography related equipment. Furthermore, it is expected that it increase to 650,000 in the whole country.
- ② It is expected that the number of breast cancer discoveries (registration of new cancer cases) increases to about 3,300 for two years by providing mammography and mammography related equipment and conduct the screenings. Furthermore, it is expected that it increase to 11,000 in the whole country
- ③ It is expected that the number of early stage breast cancer discoveries (up to stage 1) increases to about 840 for two years by providing mammography and mammography equipment and conduct the screenings. Furthermore, it is expected that it increase to 2,800 in the whole country.

The following indirect impacts are expected from the implementation of this Project:

- ① The earlier detection rate of the breast cancer increases by the screening system being improved.
- ② The death due to breast cancer decreases by earlier detection and the early treatment of the breast cancer.
- ③ Understanding and consideration to the breast cancer screening of Serbian people improves by strengthening the screening system and being executed the screening activities.

This Project is expected to produce the above-mentioned outcomes and impacts. It will also contribute to the improvement of women's health, as it addresses breast cancer. These facts confirm the relevance of the implementation of this Project as Japanese assistance under the Grant Aid Cooperation Program. Furthermore, it is considered that the Serbian side has a system with sufficient personnel and budget to operate and maintain the equipment to be

procured in this Project and to maintain the accuracy of mammograms.

At the same time, it is recommended that the Serbian side earnestly address the following problems and recommendations for smoother and more effective implementation of this Project.

(1) Introduction and use of related information for breast cancer screening

It is necessary that measures be taken not only for the maintenance of the medical equipment for breast cancer screening but also for the establishment of appropriate indicators and the collection and use of important statistical data for the evaluation of the activities and outcomes of the breast cancer screening program. For example, it is important to gather and maintain appropriate data including not only the number (percentage) of people who have had the screening but also the number (percentage) of people who require further examination, the number (percentage) of people who have had a further examination, the number (percentage) of cases in which cancer has been detected and the number (percentage) of cases in which early-stage cancer has been detected. Regular monitoring and evaluation of these indicators following completion of the implementation of this Project will be essential for improving the efficiency of facility operation and the quality of the breast cancer screening services. It is expected that the establishment of such an operating system will lead to a reduction in the number of deaths due to breast cancer, which is the overall goal of this Project.

(2) Development of the capacity of the radiologists and radiological technologists working at the target facilities

The members of the working group established for the National Program for Prevention of Breast Cancer of Serbia prepared a plan for training in mammography for the medical personnel (radiologists and radiographers) working at the medical facilities at which this Project is to be implemented, and selected the training institutions and training periods. In the prepared training plan, training of the personnel concerned will be completed at all the facilities concerned by the first quarter of 2011, previous to the installation of the equipment to be provided in this Project. It is important that the medical personnel be provided with sufficient training without delay, as this will contribute to a qualitative and quantitative improvement in the screening services.

(3) Accuracy and quality control of mammogram for breast cancer screening

It is considered that the establishment in Serbia of an organization corresponding to the Japanese Central Committee on Quality Control of Mammographic Screening together with the high-level standardization of mammography accuracy and quality throughout the country will form the basis of the appropriate operation of the breast cancer screening program, which will lead to a reduction in the number of deaths from breast cancer. The MoH of Serbia fully

recognized the importance of accuracy control in mammography and expressed the intention to establish an accuracy control committee composed of the members of the National Program for Prevention of Breast Cancer and relevant personnel from the Vinca Institute of Nuclear Sciences; this committee would be responsible for radiological accuracy control in Serbia. The establishment of a committee for accuracy control in mammography will be extremely important in the operation of the screening services, as the operation of such a committee will contribute significantly to ensuring that mammography is of equal quality (in terms of the quality of mammograms) at medical facilities in both rural areas and the capital, and to the diagnosis of breast cancer at the rural medical facilities.

This Project plans to provide technical assistance through soft component by a Japanese consultant as part of this Project for the acquisition and establishment of the techniques for appropriate accuracy and quality control of the procured equipment and mammograms.

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Location Map

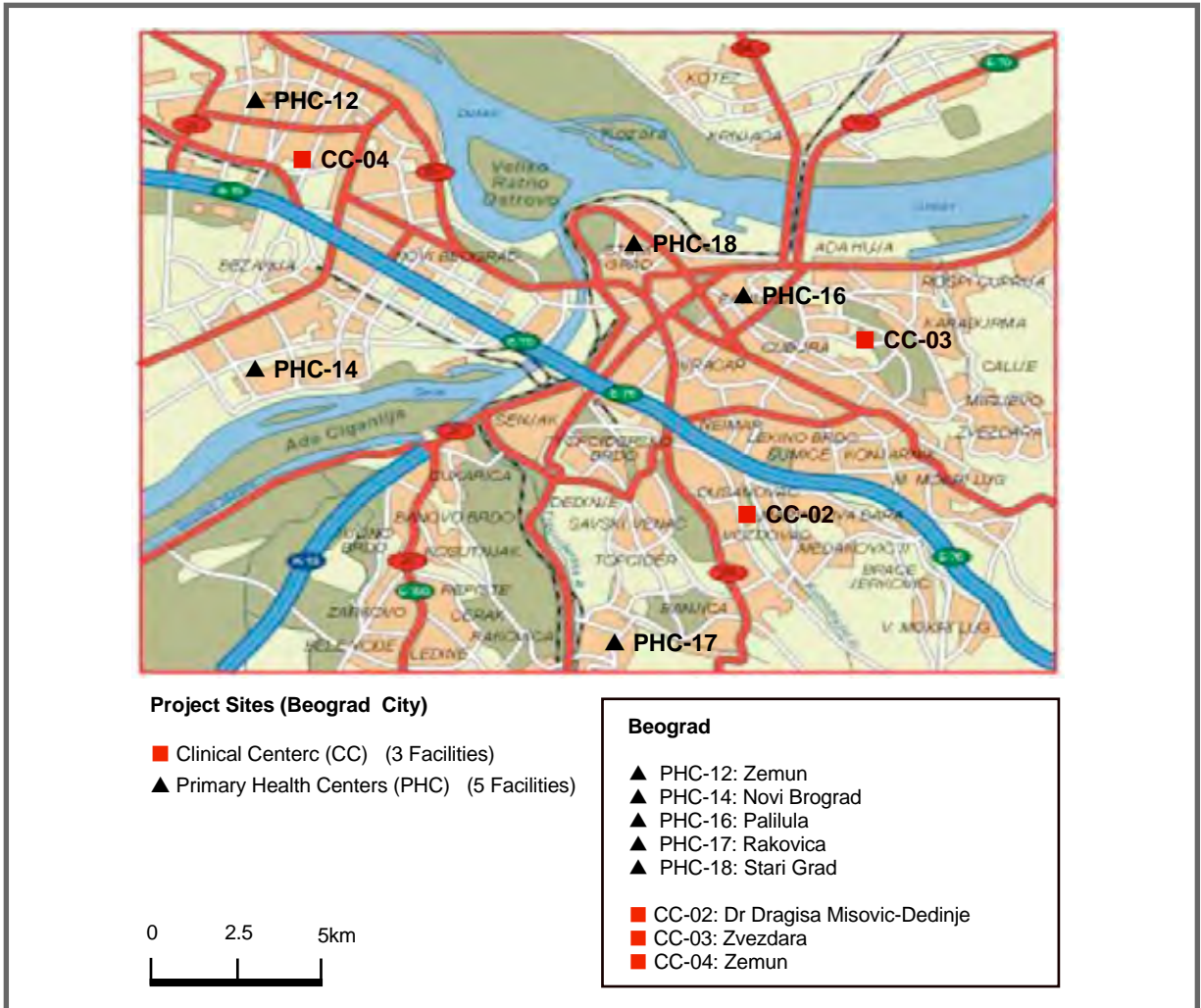


Figure 1 Project Site (In Beograd City)



Figure 2 Project Sites (Out of Beograd City)

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Abbreviations

ALIMS	Medicines and Medical Devices Agency of Serbia
A/P	Authorization to Pay
B/A	Banking Arrangement
CC	Clinical Center
CHC	Clinical Hospital Center
CIDA	Canadian International Development Agency
CR System	Computed Radiography System
EUREF	European Reference Organization for Quality Assured Breast Screening & Diagnostic Services
E/N	Exchange of Notes
FTA	Free Trade Agreement
EU	European Union
G/A	Grant Agreement
GDP	Gross Domestic Product
GH/HC	General Hospital / Health Center
GNI	Gross National Income
JICA	Japan International Cooperation Agency
MoH	Ministry of Health
PHC/DZ	Primary Health Center / Dom Zdravlja
PRSP	Poverty Reduction Strategy Papers
ODA	Official Development Assistance
UNICEF	The United Nations Children's Fund
VINCA	Institute of Nuclear Sciences
WB	World Bank
WHO	World Health Organization

Chapter 1 Background of the Project

CHAPTER 1 BACKGROUND OF THE PROJECT

1-1 Background of the Project

With regard to breast cancer, which has a high incidence rate (25% of all cases of cancer in females) in the Republic of Serbia (hereinafter referred to as “Serbia”), it is said that in developed countries more than 70% of cases are detected in the early stage and of these more than 90% achieve recovery, while in Serbia the early-stage detection rate remains at 25%, with a high ratio of patients dying within 3 years of the onset of the disease. The delay in the detection of cancer leads to the high mortality rate, and also increases the physical and economical burden on patients as well as on their families, due to the need for treatment for advanced cancer. It also increases the financial burden borne by the state due to expenditure on treatments using anti-cancer agents.

In this situation, in 2005 the Ministry of Health (hereinafter referred to as “MoH”) of Serbia established the “National Guidelines for Cancer Prevention”, and in 2007 made the program for cancer diagnosis and treatment the top-priority issue in its “Operating Plan for Health Policies”. The activities to promote early-stage detection of breast cancer in particular are clearly mentioned in this program, together with the need to establish diagnostic techniques and to improve cancer treatment.

Table 1.1 Major cancers in females in Central Serbia (numbers reported)

ICD-10	Location of cancer	Number of newly-diagnosed cases	Percentage of all cases (%)	Number of deaths	Percentage of all cases (%)
C50	Breast	2,617	22 (Note 1)	1,115	18 (Note 1)
C18-C20	Colon, rectum and rectosigmoid junction	1,145	10	759	12
C53	Cervix	948	8	370	6
C34	Bronchium and lung	797	7	705	11
C54	Endometrium	702	6	98	2
	Others	5,481	47	3,095	51
	Total	11,690	100	6,142	100

Remarks: Serbia consists of the 17 districts of Central Serbia and the 7 districts of the Autonomous Province of Vojvodina in the north. The population ratio between Central Serbia and the Autonomous Province of Vojvodina is approximately 73:27.

Note 1: The figures are the percentage of newly-reported cancer patients, and are for Central Serbia only; they therefore differ from the figures given in the text (eg 25% and/or 19%).

Source : Health Statistical Yearbook of the Republic of Serbia 2007

Against this background, the Government of Serbia requested grant aid cooperation from the government of Japan in August 2006 for the procurement of screening medical

equipment (mammography units and ultrasound scanners) to be installed at 45 health and medical facilities in the country in order to establish an early-stage breast cancer detection system (a free medical check-up system). In response to this request, the Japan International Cooperation Agency (hereinafter referred to as “JICA”) dispatched the First Preparatory Survey (hereinafter referred to as “Preparatory Survey (1)”) team to Serbia from late May to late June 2009 in order to examine the necessity for and relevance of the requested project and to clarify the details of the facilities to be equipped, together with their condition and scale. The survey discovered that the prevention of breast cancer is an important issue in the health sector of Serbia, and in February 2009 the National Assembly approved the “National Program for Prevention of Breast Cancer,” which urgently requires the establishment of a screening system including the procurement of the related equipment. Thus it has been confirmed that the requested project is in accordance with the above-mentioned program. It was also confirmed that a Working Group consisting of 12 experts appointed by the Minister of Health in April 2009 (medical doctors and researchers from the MoH, the Institute of Public Health of Serbia, the Cancer Centers, Tertiary Hospitals, the Health Insurance Fund, etc) has already been established for the implementation and operation of the above mentioned program, and that the training of the radiologists and radiographers needed for the implementation of the screening is to be planned and implemented accordingly.

As for the facilities to be equipped and the equipment to be supplied, around half of the facilities originally listed have been deleted from the request list since they had been equipped by the self-reliance efforts of the Serbian Government as well as through Italian aid after the request to the Japanese Government had been made. There was also a request for modification of the facility list in view of the number of people expected to have cancer screenings, and the availability of medical specialists and technical experts to be assigned within each municipality. Therefore, the survey team carried out its survey at a total of 44 facilities.

On the basis of the field survey results, the survey team held discussions with the counterparts and set up the following criteria for the selection of facilities to be equipped;

- 1) 1 set of mammography unit to be supplied per 12,000 to 14,000 of population eligible for breast cancer check-up (females in the age range 45 to 69 years old) in each District, and
- 2) Each facility must have already assigned a radiologist and a radiographer, and they are expected to complete the training to be implemented by the working group by March 2011, when the requested equipment is to be supplied. In line with these criteria, the survey team reorganized the requested items. As a result, a revised request was made for analog mammography unit with mammography related equipment, such as a X-ray film processor, schaukasten (hereinafter referred to as “X-ray film viewer”) and phantom for 30 facilities,

digital mammography unit with mammography related equipment for 2 facilities and mammography related equipment for 7 facilities (39 facilities in total).

Then, the Second Preparatory Survey (hereinafter referred to as “Preparatory Survey (2)”) team was sent to Serbia from late October to late November 2009 in order to reconfirm the need for and relevance of the Project, to draw up the outline design and operating plan as an appropriate project under the Japanese grant aid program and to estimate the costs of the Project.

The survey team confirmed that pilot screening and publicity activities had been carried out in each district using mobile clinics since June 2009. Also during the explanation of the draft Outline Design (March 2010), it was confirmed that the number of people being screened was on the increase. Moreover, the screening activities are also providing the transfer of technology in mammography by the radiologists and radiological technologists of the Institute of Radiology and Oncology, Serbia and the Clinical Center Nis to those working at the rural medical facilities.

1-2 Conditions of the Project Sites and Surrounding Area

1-2-1 Natural Conditions

Serbia is a landlocked country bordered to the north, east, south and west by Hungary, Romania and Bulgaria, Macedonia and Albania, and Croatia, Bosnia-Herzegovina and Montenegro, respectively. It is almost located at the center of the Balkan Peninsula, the large river, such as the Sava River, the Drava River, and the Danube River, etc, crossing to the northern part in the country.

The part of plains is continental climate, and the yearly difference of the temperature is large. Precipitation is a little.

There is a little difference in the natural condition between regions though the Project sites scattered across the country. It is very important to secure appropriate environment systems of mammography, and the temperature management by air conditioning facilities is necessary in summer and winter seasons. Moreover, it is noted that the road might freeze when the equipment is transported in winter.

1-2-2 Environmental and Social Considerations

Developing and fixing solutions are feared to influence harmfully to the environment used for the X-ray film processors. Those solutions are collecting by private companies in Serbia.

Chapter 2 Contents of the Project

CHAPTER 2 CONTENTS OF THE PROJECT

2-1 Basic Concept of the Project

(1) Overall goal and project goal

The Health Development Plan for Serbia complies with the “Health Policy of Serbia” adopted in February 2002 and the “Reform Strategy and Action Plan for a Healthcare Vision and Healthcare System (2009/2011) “ developed in line with the Policy. In February 2009, the National Assembly approved the National Program for Prevention of Breast Cancer in line with the Healthcare Development Plan. This program urgently requires the establishment of a system of breast cancer screening, including the procurement of the equipment needed for such screenings.

This being the situation, the Project aims to contribute to an increase in the number of women receiving a screening for breast cancer and early-stage detection of breast cancer.

(2) Outline of the Project

In order to achieve the above-mentioned goals, the Project plans to implement the training of the radiologists and radiographers who will carry out the breast cancer screening, to engage in promotional and educational activities to encourage the appropriate people to have a screening, and to develop infrastructure, including medical equipment. Furthermore, the Project aims to establish a system of accuracy control that will enable the creation of uniform mammograms at health facilities so that the photographed images can be properly diagnosed. It is expected that as a result a greater number (percentage) of people will be eligible for breast cancer screening (females in the age range 45 to 69 years old) and at the same time breast cancer will be detected at an early stage (Stage 0: cancer remains within the mammary gland and Stage 1: cancer tissue of less than 2cm diameter with no metastases to the lymph nodes). To this end, the Project will procure the mammography equipment and mammography related equipment needed for breast cancer screening and diagnosis.

(3) Indices that measures Projects’ Outcomes

The number of breast cancer screenings, the number of discoveries of breast cancers, and the number of earlier detection (up to stage 1) increase in the Project sites (The target site of the Project is correspond to about 30% in the country).

Table 2.1 Indices that Shows Accomplishment of a Goal of the Project

Indices	Whole Country (Year of '08 & '09 total)	Whole Country (Year of '13 & '14 total)	Outcomes by Japanese Assistance (Year of '13 & '14 total)
Number of screenings	① 9,000	④ 650,000	⑦ 195,000
Number of discoveries of breast cancer (registration of new cases)	② 8,000	⑤ 11,250	⑧ 3,375
Number of earlier detection of breast cancer (up to stage 1)	③ 2,000	⑥ 2,812	⑨ 843

Source: Preparatory Survey (2) Team and related Japanese members concerned, 2010

(Idea of indices setting)

- The index is set the breast cancer screening frequency in Serbia is once every two years in total of two years.
- Total 4,800 screenings by a mammography unit in a year (20 screenings/day x 240 days/year), then, total 9,600 screenings in two years. A screening frequency is once in two years, if screening rate is 100%, the number of mammography is requires 135 units (130 million target women for screening x 9,600/unit). Total 39 facilities improved by the Japanese assistance, therefore, it will assume to contribute that almost 30% of total numbers of screening in the country.

(Setting method of each index)

- ① The breast cancer screening executed in a Serbia only examines the Pilot by the mobile screening car at present (begin in June, 2009). The figures adopted here, none in 2008, only June to December 2009.
- ② The total number of breast cancer is 8,000 (4,000 per year x 2 years).
- ③ Number of cancer discoveries of earlier detection rate (EDR) in Serbia is about 25% (EDR = number of earlier detecting breast cancer / total number of breast cancer), therefore, number of breast cancer earlier detecting is 2,000.
- ④ About 1.3 million object of the breast cancer screening (women of 45 to 69 years old) in Serbia, if breast cancer screening rate is assumed to be 50% (1.3 million women x 50%), totally 650 thousand women will be screenings.
- ⑤ It is in the situation in which a new registration numbers of the breast cancer by Serbian statistical data is about 4,000 women yearly in last 3 years. This figure is patients who consulted by doctors with abnormality of the body. On the other hand, the breast cancer women will be found from about 0.5% of those who screening the

breast cancer according to the Pilot screening by the mobile screening car that has been begun since 2009 (new breast cancer registration rate). If there are 650 thousand women are going to screening in two years, about 3,250 will be found as new breast cancer women ($650,000 \times 0.5\%$). The total numbers of the breast cancer women in two years is assumed that 11,250 women will be found in the country ($4,000$ is yearly potential breast cancer women $\times 2$ years, plus 3,250, totally 11,250).

- ⑥ It will 2,812 will be found with earlier detecting (up to stage 1) breast cancer ($11,250 \times 25\%$).
- ⑦ The Japanese assistance will contribute of 30% benefit in a nationwide; therefore, 650 thousand women $\times 30\%$, totally 195,000 women are expected to as total screenings in two years.
- ⑧ The Japanese assistance will contribute of 30% benefit in a nationwide; therefore, 11,250 women $\times 30\%$, totally 3,375 women are expected to as new breast cancer (new breast cancer registration women).
- ⑨ The Japanese assistance will contribute of 30% benefit in a nationwide: therefore, $2,812 \times 30\%$, totally 843 women are expected to as earlier detecting breast cancer.

(4) Reliability (Important assumption)

- The training for capacity improvement and the technology necessary for the breast cancer screening by the Working Group of the National Program for Prevention of Breast Cancer intended for the radiologists and the radiographers are executed according to the planned schedule.
- The Working Group of the National Program for Prevention of Breast Cancer and VINCA are strengthening the system of the quality control of breast cancer screening, such as the Central Committee on Quality Control of Mammographic Screening in Japan.

2-2 Outline Design of the Japanese Assistance

The outline design of this Project will be planned in accordance with the design policy, which will be defined in consideration of the specialist nature of this Project and the actual circumstances in Serbia.

2-2-1 Design Policy

(1) Consideration process

The Government of Serbia initially requested the procurement of mammography units (digital type and analog type) and ultrasound scanners, to be installed at 45 health and medical facilities in the country. However, the preparatory surveys (1 and 2) conducted in June and

November 2009 examined the facilities to be equipped and the details of the requested equipment. As a result, a revised request was made for the procurement of mammography units with peripheral equipment (7 items in total) for 39 facilities.

(2) Design Policy

1) Basic Policy

The Project will support the procurement of mammography unit and peripheral equipment necessary to establish the first breast cancer screening system to be attempted in Serbia. In the cancer screening system, it is important that all the women examined receive cancer-screening diagnosis impartially. In formulating the basic concept of this Project, consideration was given to securing and promoting impartiality, and public health centers (PHC/DZ), which will be the primary access facilities for the women to be examined, and key hospitals in the local areas were selected as the target facilities for this Project. As the selection criteria for the target facilities, the following two factors were considered:

- 1 set of mammography unit to be supplied per 12,000 to 14,000 of population eligible for breast cancer screening (females in the age range 45 to 69 years old) in each District
- Each facility must have already assigned a radiologist and a radiographer, and they are expected to complete the training to be implemented by the working group by March 2011, when the requested equipment is to be supplied

Supporting the activities of Serbia, which aims to become an EU member, meets our policy of supporting Serbia. The EU has already developed support in this field, but the MoH of Serbia will coordinate the support activities of the EU and Japan to ensure that both projects are implemented effectively.

2) Policy for establishing the grade of the equipment

(The equipment shall be mammography unit for breast cancer screening)

In the health facilities which will conduct breast cancer screening under the National Program for Prevention of Breast Cancer, it is planned to photograph 20 persons per day with one mammography unit. In practice, at least 3 persons are photographed 4 times (2 times each for the left and right breast) per hour, so the mammography unit is required to be capable of 12 radiography operations per hour. The radiographers work for about 3 to 4 hours per day in 2 shifts and the mammography unit must be capable of electric C-arm up/down movement and rotation so that operation of the equipment is no burden on the radiologists.

3) Policy for the system of importing medical equipment into Serbia and ensuring the proper after-sales service

(The equipment shall be registered in ALIMS, the medical equipment registration agency of Serbia)

ALIMS is an acronym for the Serbian name of the Medicines and Medical Devices Agency of Serbia, the registration agency for medicines and medical devices in Serbia. The medical equipment to be registered in ALIMS must meet the requirements provided in the Serbian edition of the instruction manual and an agent must be appointed in Serbia to respond to inquiries about the medical equipment, and also after-sales service for the equipment must be provided. In addition, Serbia is aiming to become an EU member and is in the process of establishing rules for medical equipment standards which comply with EUREF (European Reference Organization for Quality Assured Breast Screening and Diagnostic Services) standards.

From the above viewpoint, it is essential that the equipment is procured on the basis of the maintenance system registered with ALIMS, and the first step is that the procured equipment complies with EUREF standards.

4) Policy for the quality/accuracy control of the photographic images

Inspection equipment shall be considered for quality control of the photographic images and for equipment accuracy control.

The purpose of breast cancer screening is to detect any tumor shadows or tiny calcified spots in the breast. However, the breasts are composed of soft tissue such as fat tissue, mammary gland tissue and mammary gland interstitial tissue, which have little difference in X-ray absorption. To obtain high image contrast, it is necessary to obtain sharp image quality by using low-energy X-ray and high-contrast film. In breast cancer screening with mammography unit, it is important to obtain uniform image quality among the health facilities and quality images that are always stable. For this purpose, it is necessary to provide the facilities with standardized quality control processes. Therefore, it is planned to at least procure the quality control equipment necessary for such processes. In practice, it is planned to procure the phantom necessary for quality / accuracy control of the mammography, the sensitometer and densitometer necessary for quality / accuracy control of the X-ray film processor, and the dedicated X-ray film viewer necessary for correct image interpretation.

5) Policy for the work schedule

The work schedule for installation of the procured equipment and completion of the work will be a period of 12 months in principle, but the work schedule will be planned with due consideration for the 39 sites where the procured equipment will be installed. If the medical

and clinical care services at any of the facilities should be stopped during the period of transporting and installing the equipment and devices, the transportation and installation schedule will be planned to minimize the effect on the medical care services. The soft component plan will follow about 3 months after the handover of the equipment, for the purpose of enhancing the quality / accuracy control of photographic images. Therefore, the entire work schedule of this Project, including the soft component plan, is expected to be completed in approximately 15 months.

2-2-2 Basic Plan (Equipment Plan)

(1) Overall Plan

Of the planned equipment, the mammography unit and X-ray film processor require installation. In particularly installation of the mammography unit will require some targeted facilities to arrange renovation works (such as lead shielding for x-ray protection in the room where the equipment will be installed, and the setting up of cabinet panels. Refer to the Outline Design Figure mentioned later). Thus such works must have been completed before the planned equipment is transported into the facility.

The planned equipment is fundamental and essential for the provision of breast cancer screening, and will be used for the purpose of expanding the screening services and diagnosing images.

(2) Outline of Composition and Specifications of Planned Equipment

The composition and specifications of the planned equipment are outlined below.

① Digital Mammography

The digital mammography unit will basically be the general-purpose equipment registered at ALIMS. As it will be required to provide long-time breast cancer screening operation, it is essential that it has the following specifications:

- The generator shall provide high radio frequency.
- Molybdenum, and molybdenum and rhodium shall be selectable for the anode and filter combination.
- The bulb heat storage capacity shall be 300kHU or more and the cooling power shall be high.
- The equipment shall be multi-focus type and have an automatic exposure control mode.
- The detector shall have a size of about 24cm×30cm or more.
- The image interpretation workstation shall be equipped with 2 monitor units with a resolution of 5 megapixels and display performance of 1 pixel/dot.

In addition, the equipment shall be equipped with components for daily quality control equivalent to ACR phantom and step phantom.

② Analog Mammography

The analog mammography unit will be the general-purpose equipment registered at ALIMS, like the digital mammography mentioned-above. As it will be required to provide long-time breast cancer screening operation, it is essential that it has the following specifications:

- The generator shall provide high radio frequency.
- Molybdenum, and molybdenum and rhodium shall be selectable for the anode and filter combination.
- The bulb heat storage capacity shall be 300kHU or more and the cooling power shall be high.
- The equipment shall be multi-focus type and have an automatic exposure control mode.
- The size of the cassette holder shall be selectable from 18cm×24cm and 24cm×30cm.

In addition, the Screen Film (S/F) system shall be equipped with a component

equivalent to ACR phantom, and the CR system with components equivalent to ACR phantom and step phantom for daily quality control.

③ CR System

The CR system digitalizes the analog mammography unit. It consists of an image plate (called "IP") which is inserted into the cassette holder, a CR receiver which reads the data recorded in the image plate, and a reading station for operating the CR receiver. These system components will be models which are dedicated to displaying mammary gland images and capable of producing high quality images of mammary glands. In detail, the pitch size will be 50 μ m or less and the resolution will be specified at 20 pixels or more per 1mm.

④ Dry Imager

The dry imager is for making hard copies of the images digitized by the CR system. There are two imaging systems for use with the medical dry imager: the "thermal system" in which images are directly generated on thermosensitive film by a thermal head, and the "silver-halide dry system" in which silver-halide film is exposed to a laser beam and developed by heat. Both systems can be adopted if they meet the specifications for ensuring that breast images are printed with high quality. In more detail, the resolution shall be 500dpi (dot density per inch) or more and the film shall be dedicated to mammary gland images for printing high quality images.

⑤ X-ray Film Processor

The X-ray film processor is for developing film on which mammary gland images have been radiographed by the analog mammography. It will be a model which is dedicated to mammary gland images and capable of printing high sensitivity film developed for mammary gland images. In more detail, the developing time and temperature parameters will be changeable depending upon the film specifications and it is desirable that the developing liquid tank will have a high capacity in order to keep the developing liquid concentration as constant as possible. It is also planned to procure a high sensitivity film cassette and screen which are dedicated to mammary gland radiography.

⑥ X-ray Film Viewer

It is necessary to observe the images radiographed by the mammography under image interpreting conditions which are always constant. Therefore, it is planned to procure a film viewer model dedicated to mammary gland images. In more detail, the viewer shall be specified for an illuminated surface brightness of 3,500cd/m² or more, and shall have a

brightness control function and masking mechanism. In addition, consideration shall be given to ensuring a screen size that is easy for comparing new and past mammary gland images.

(3) Specifications of Planned Equipment

The main equipment planned for this Project will have the specifications as shown in Table 2.3 below.

Table 2.3 Specifications of the Equipment

No	Equipment	Q'ty	Components and Specifications	Purpose for Use Level of Specifications
1	Digital Mammography	2	<ul style="list-style-type: none"> - C-arm rotation type & range: Motorized, from -135 to +180 degree or wider range - Bucky Device: 24 x 29 cm or more - X-ray tube unit: 300KHU or equivalent performance - X-ray generator: From 25 – 35kV or wider range 	The Equipment is specifications of more than 20 screenings a day that can be taken a mammography.
2	Analogue Mammography (A)	18	<ul style="list-style-type: none"> - C-arm rotation type & range: Motorized, from -135 to +180 degree or wider range - X-ray tube unit: 300KHU or equivalent performance - X-ray generator: From 23 – 35kV or wider range - CR System interface kit: Equipped 	The Equipment is specifications of more than 20 screenings a day that can be taken a mammography.
3	Analogue Mammography (B)	12	<ul style="list-style-type: none"> - C-arm rotation type & range: Motorized, from -135 to +180 degree or wider range - X-ray tube unit: 300KHU or equivalent performance - X-ray generator: From 23 – 35kV or wider range 	The Equipment is specifications of more than 20 screenings a day that can be taken a mammography.
4	CR System	23	<ul style="list-style-type: none"> - System components: CR reader, Acquisition workstation, PC for data storage, IP cassette - CR reader spatial resolution: 20 pixels/mm or more - Pixel size: 50 micrometer or less - Monitor: 17 inches or larger 	The System converts analogue imaging data into digital data. Resolution shall over 20 pixels/mm.
5	Dry Imager	25	<ul style="list-style-type: none"> - Image resolution: 500dpi or more - Pixel size: 50 micrometer - Output gray level: 14 bits or more - Film supply tray: Equipped 2 or more 	The equipment prints the images processed with a CR System. Image resolution shall over 500dpi.

2-2-3 Outline Design Drawing

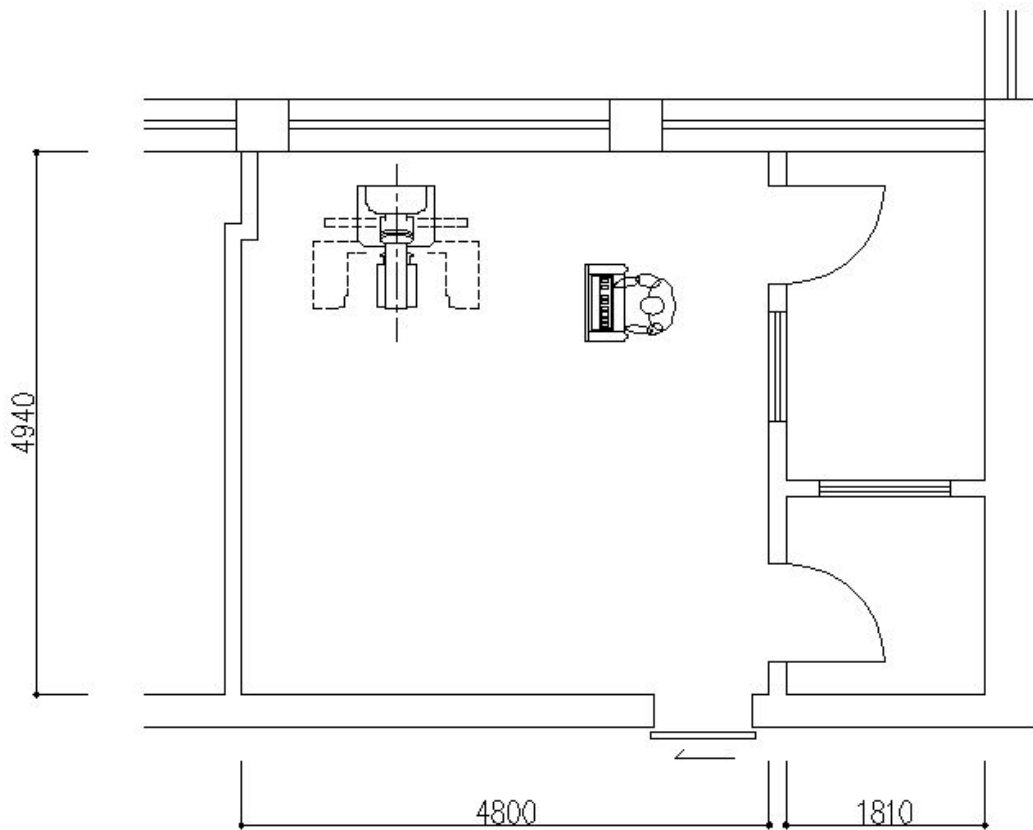
The mammography units to be procured in the Project will be installed at 32 facilities as shown in Table 2.4. The installation layout drawings (draft) for the facilities under this Project are attached hereto.

Table 2.4 Layout Plan (Draft) of Mammography in Target Medical Facilities

No.	Facility No.	Name of Facility	Equipment Package	Page
1	HC-01	General Hospital Subotica	Analog (A)	15
2	HC-02	Health Centre Senta	Analog (A)	16
3	HC-04	Health Centre Valjevo	Digital	17
4	HC-06	Health Centre Petrovac	Analog (B)	18
5	HC-08	Health Centre Negotin	Analog (B)	19
6	HC-09	General Hospital Cuprija	Analog (A)	20
7	HC-10	Health Centre Kladovo	Analog (A)	21
8	HC-11	Health Centre Knjazevac	Analog (A)	22
9	HC-12	Health Centre Zajecar	Analog (A)	23
10	HC-13	Health Centre Uzice	Analog (A)	24
11	HC-15	General Hospital Gornji Milanovac	Analog (A)	25
12	HC-16	Health Centre Kraljevo	Digital	26
13	HC-17	Health Centre Krusevac	Analog (A)	27
14	HC-18	Health Centre Aleksinac	Analog (A)	28
15	HC-19	Health Centre Pirot	Analog (B)	29
16	HC-20	General Hospital Leskovac	Analog (B)	30
17	HC-22	General Hospital Sremska Mitrovica	Analog (A)	31
18	PHC-02	Dom Zdravlja Novi Becej	Analog (B)	32
19	PHC-04	Dom Zdravlja Novi Sad	Analog (A)	33
20	PHC-06	Dom Zdravlja Bogatic	Analog (B)	34
21	PHC-07	Dom Zdravlja Kragujevac	Analog (A)	35
22	PHC-08	Dom Zdravlja Trstenik	Analog (B)	36
23	PHC-09	Dom Zdravlja Nis	Analog (A)	37
24	PHC-10	Dom Zdravlja Bujanovac	Analog (B)	38
25	PHC-11	Dom Zdravlja Grocka	Analog (B)	39
26	PHC-12	Dom Zdravlja Zemun	Analog (A)	40
27	PHC-13	Dom Zdravlja Lazarevac	Analog (A)	41
28	PHC-14	Dom Zdravlja Novi Beograd	Analog (A)	42
29	PHC-15	Dom Zdravlja Obrenovac	Analog (B)	43
30	PHC-16	Dom Zdravlja Palilula	Analog (A)	44
31	PHC-17	Dom Zdravlja Rakovica	Analog (B)	45
32	PHC-18	Dom Zdravlja Stari Grad	Analog (A)	46

No. 1

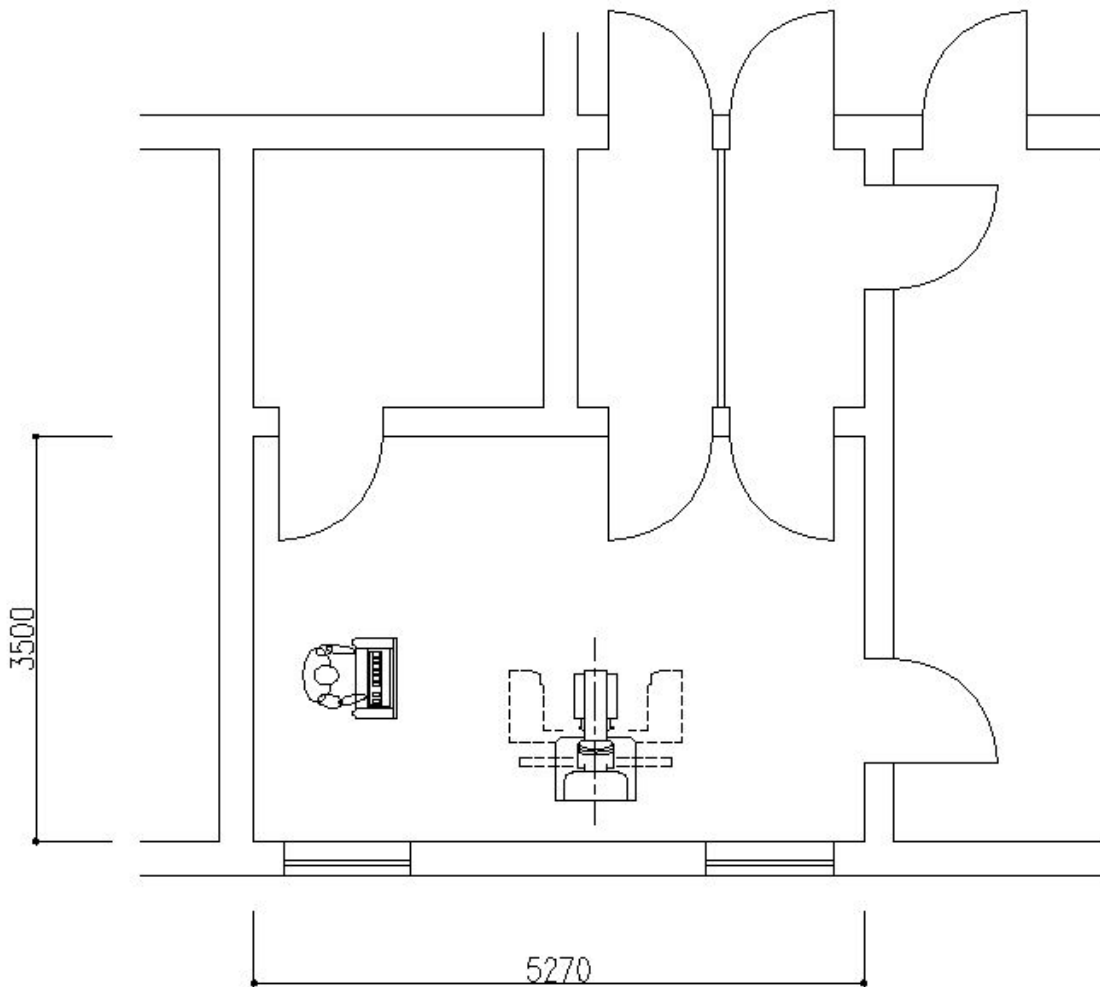
(1) Installation Plan	
• Mammography (Area)	Existing CT room (23.7 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new one
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing machine, install power supply breaker
• X-ray Film Reading Room	Install partition and shading, etc
• Approx Costs for Renovation Works	Euro 1,345 (RSD 127,000)



Site No.: HC-01	General Hospital Subotica	C.H.: 2,850 mm
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No. 2

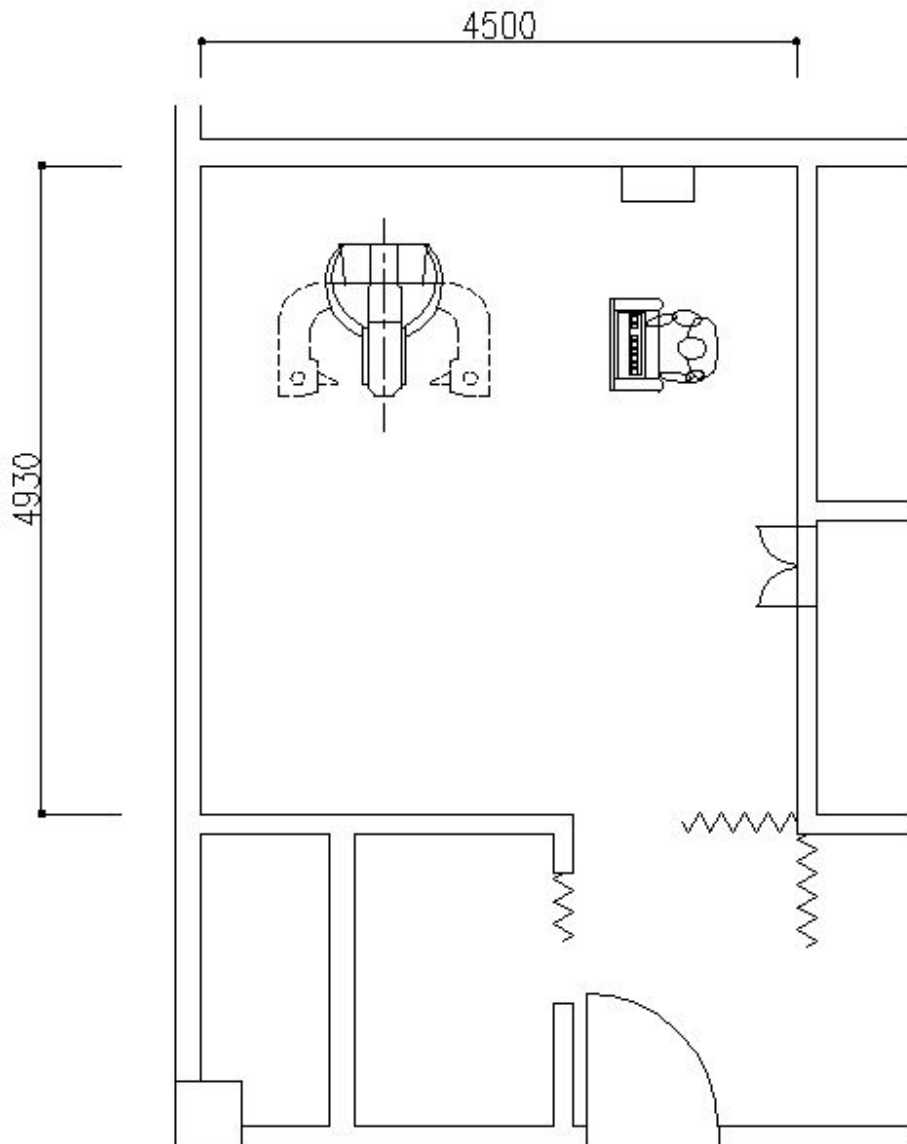
(1) Installation Plan	
• Mammography (Area)	Existing CT room (18.4 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes (Old, and not in use properly)
• Usage of Existing Mammography	Disposal
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing machine
• X-ray Film Reading Room	Install partition and shading, etc
• Approx Costs for Renovation Works	Euro 1,185 (RSD 112,000)



Site No.: HC-02	Health Centre Senta	C.H.: 3,730 mm
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No. 3

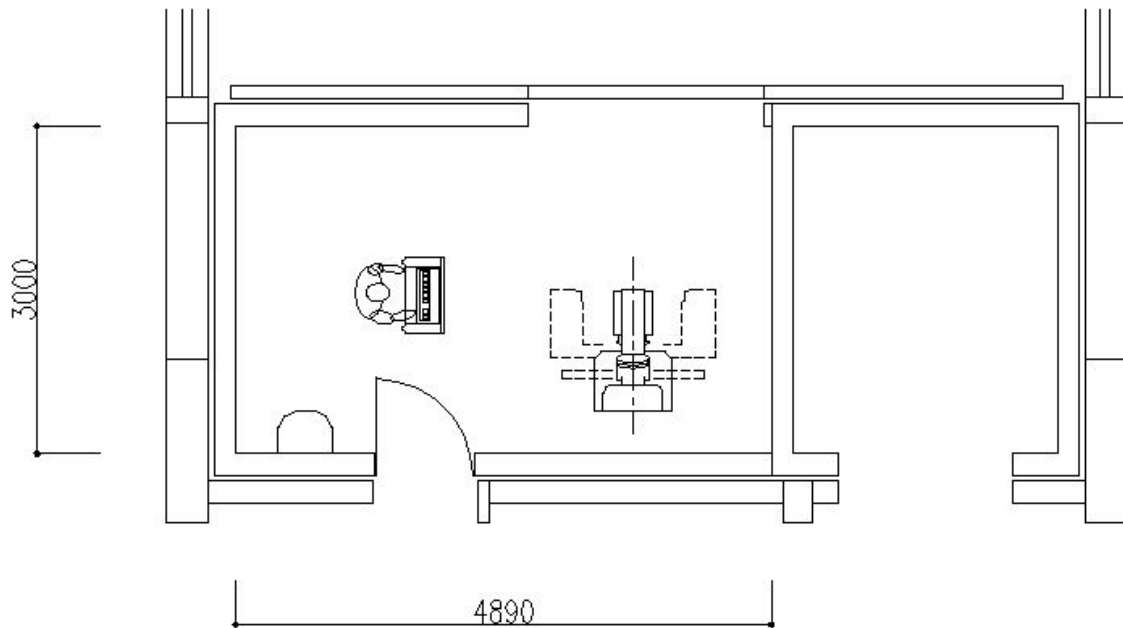
(1) Installation Plan	
• Mammography (Area)	Existing mammography room (22.2 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	Move to other room, and it uses with a new one.
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing mammography to other room
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site No.: HC-04	Health Center Valjevo	C.H.: 2,800 mm
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No. 4

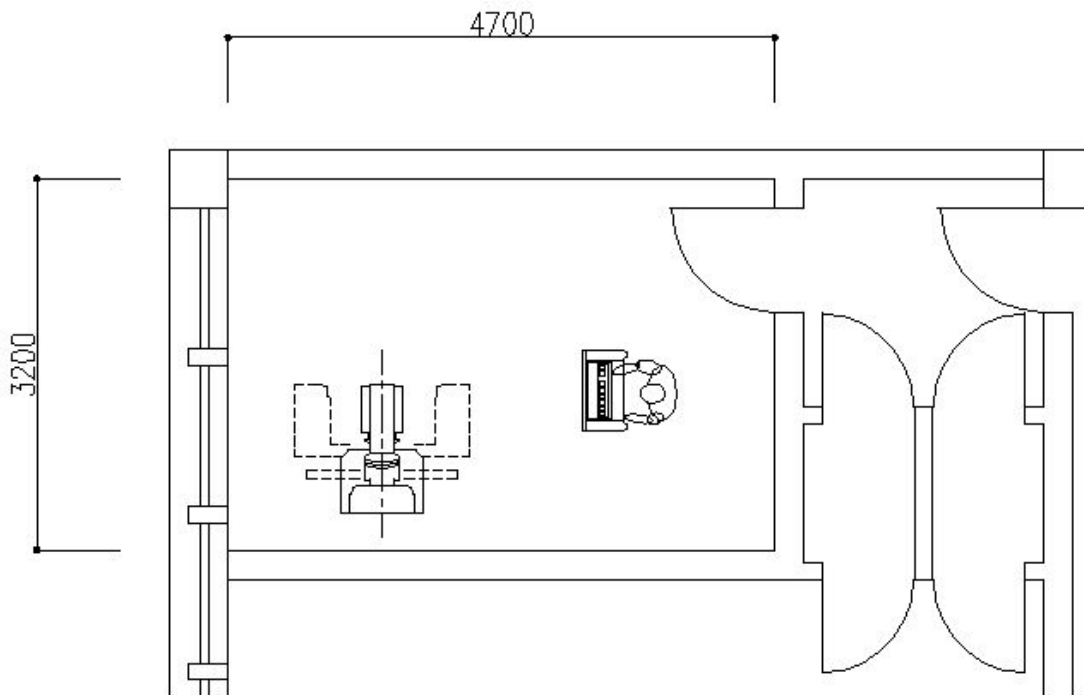
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (14.7 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing old X-ray machine
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site: HC-06	Health Center Petrovac	C.H.: 2,950 mm
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No. 5

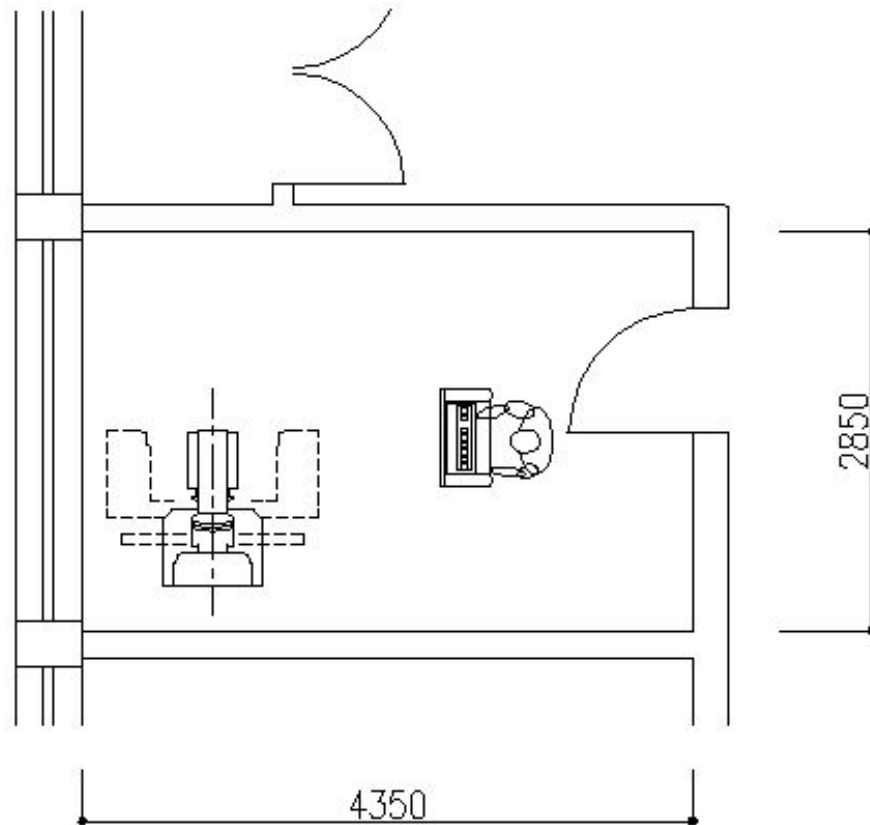
(1) Installation Plan	
• Mammography (Area)	Doctors room (15.0 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 680 (RSD 64,000)



Site: HC-08	Health Centre Negotin	C.H.: 3,440 mm
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No. 6

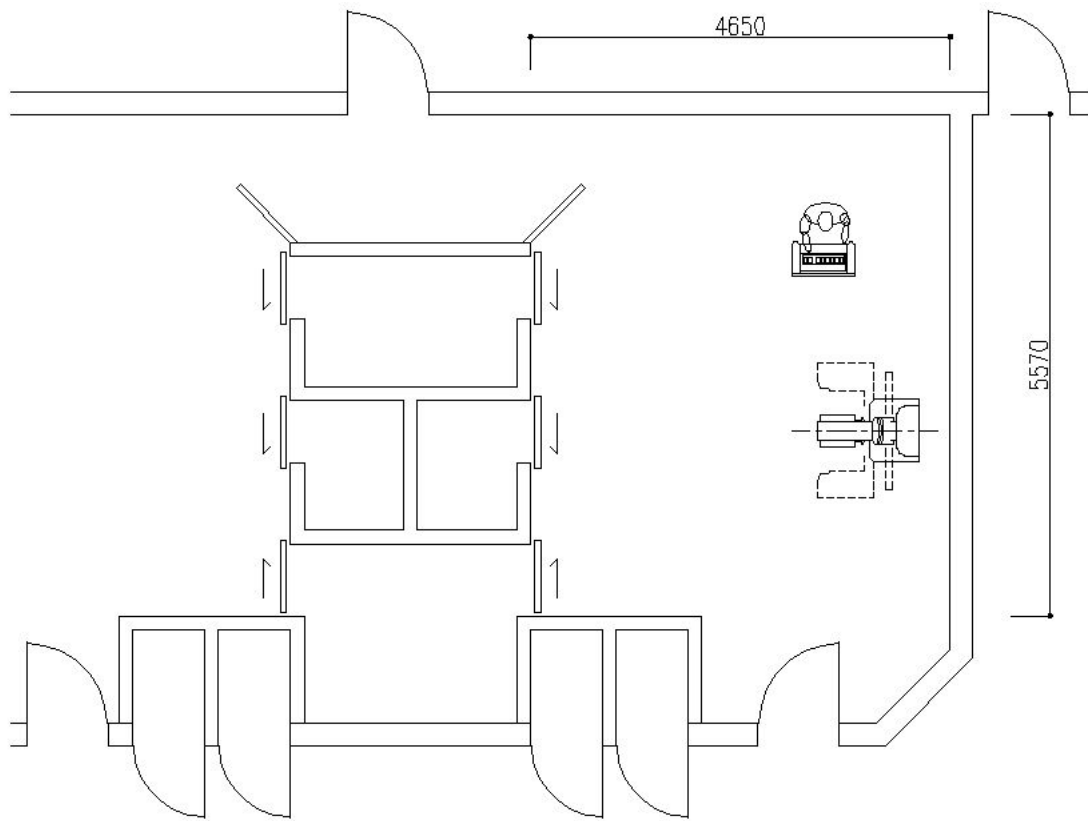
(1) Installation Plan	
• Mammography (Area)	Existing mammography room (12.4 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Processor	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes (Not in use because of unable to repair)
• Usage of Existing Mammography	Disposal
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing mammography, etc
• X-ray Film Reading Room	Install shading
• Approx Costs of Renovation Works	Euro 340 (RSD 32,000)



Site No.: HC-09	General Hospital Cuprija	C.H.: 3,030 mm
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No. 7

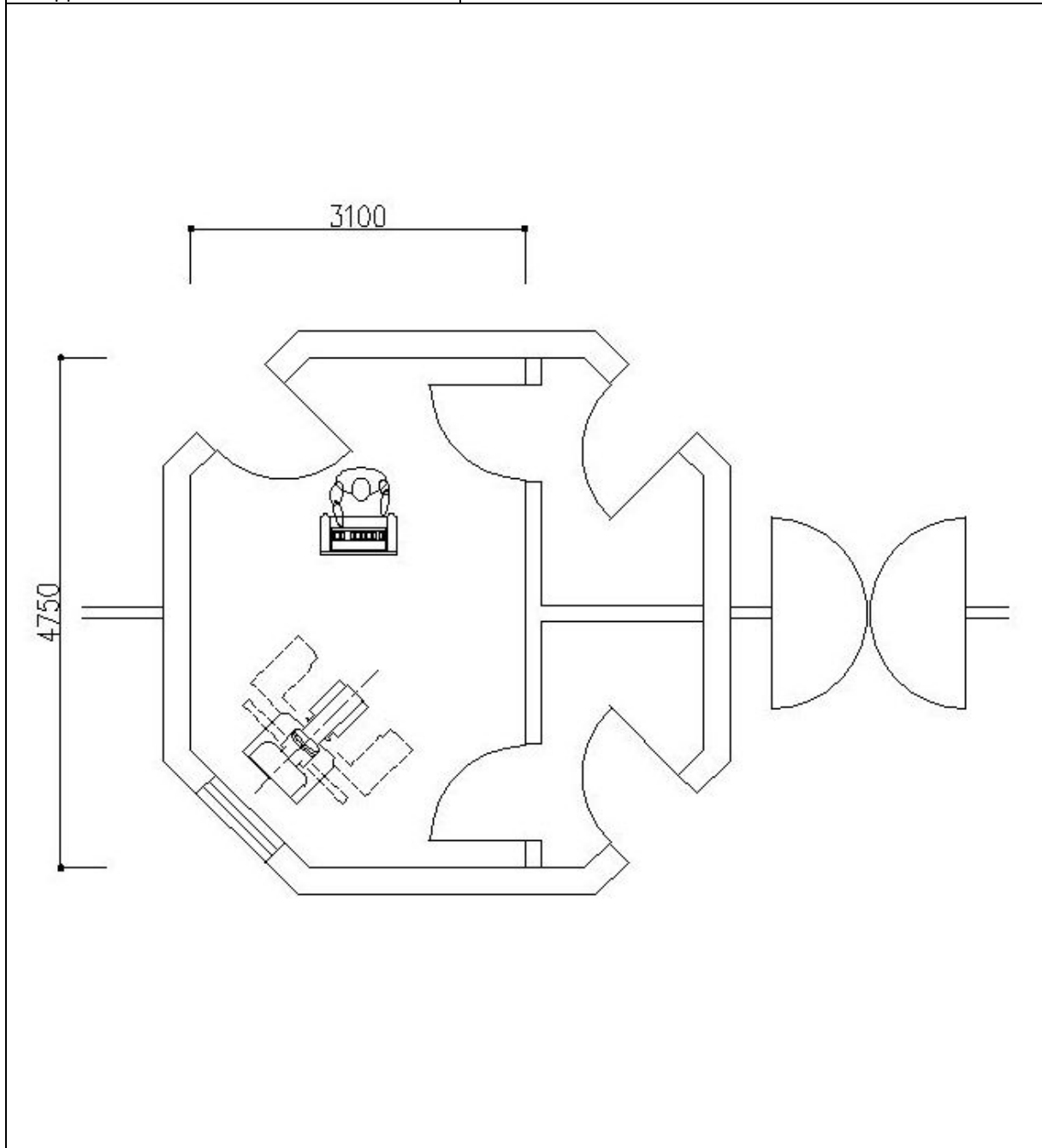
(1) Installation Plan	
• Mammography (Area)	Existing mammography room (25.9 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes (Not in use because of unable repair)
• Usage of Existing Mammography	Disposal
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing mammography, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 400 (RSD 38,000)



Site No.: HC-10	Health Centre Kladovo	C.H.: 2,850 mm
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No. 8

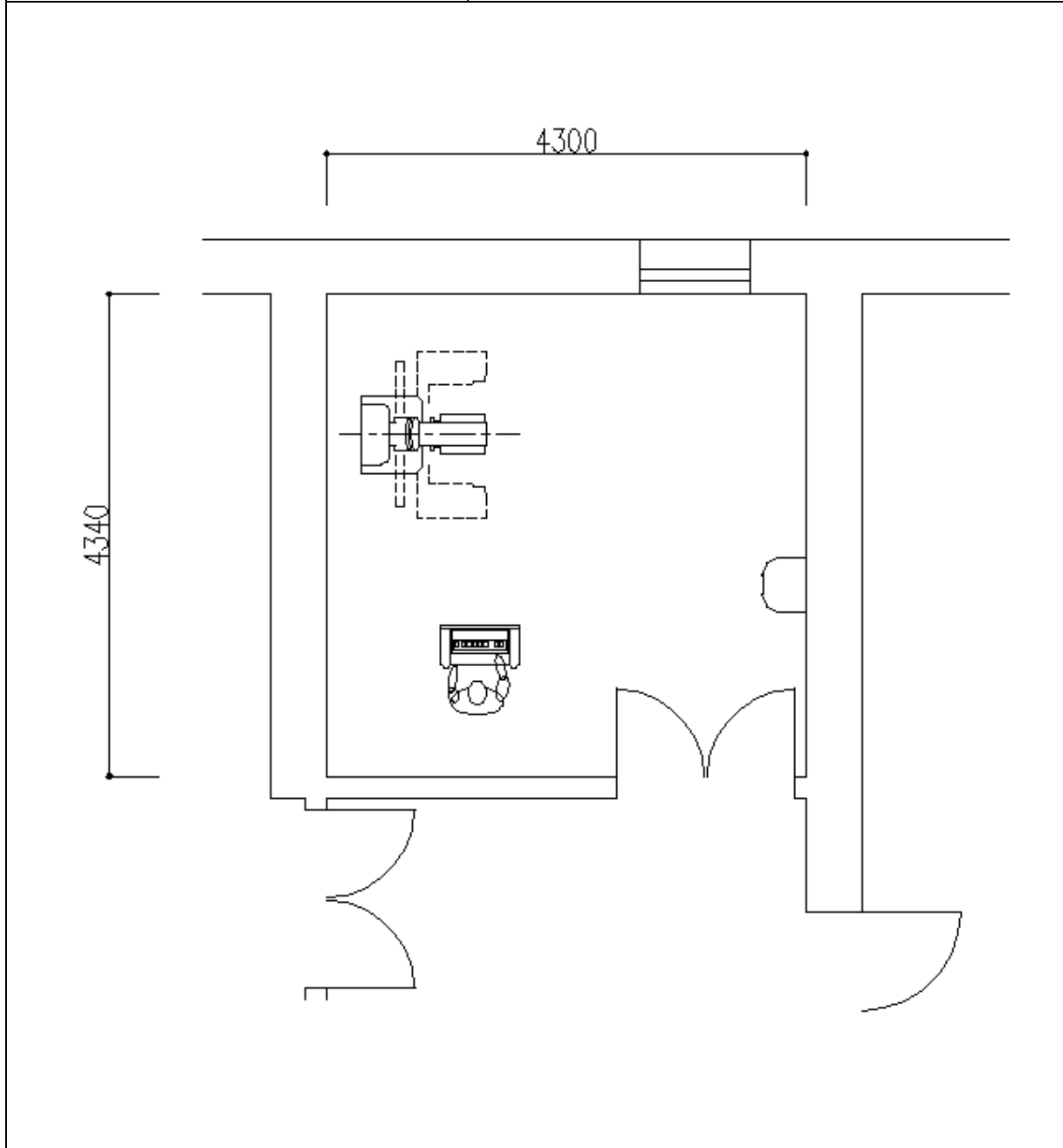
(1) Installation Plan	
• Mammography (Area)	Existing Storage Room (14.7 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 2,960 (RSD 279,000)



Site: HC-11	Health Centre Knjazevac	C.H.: 2,700 mm
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No. 9

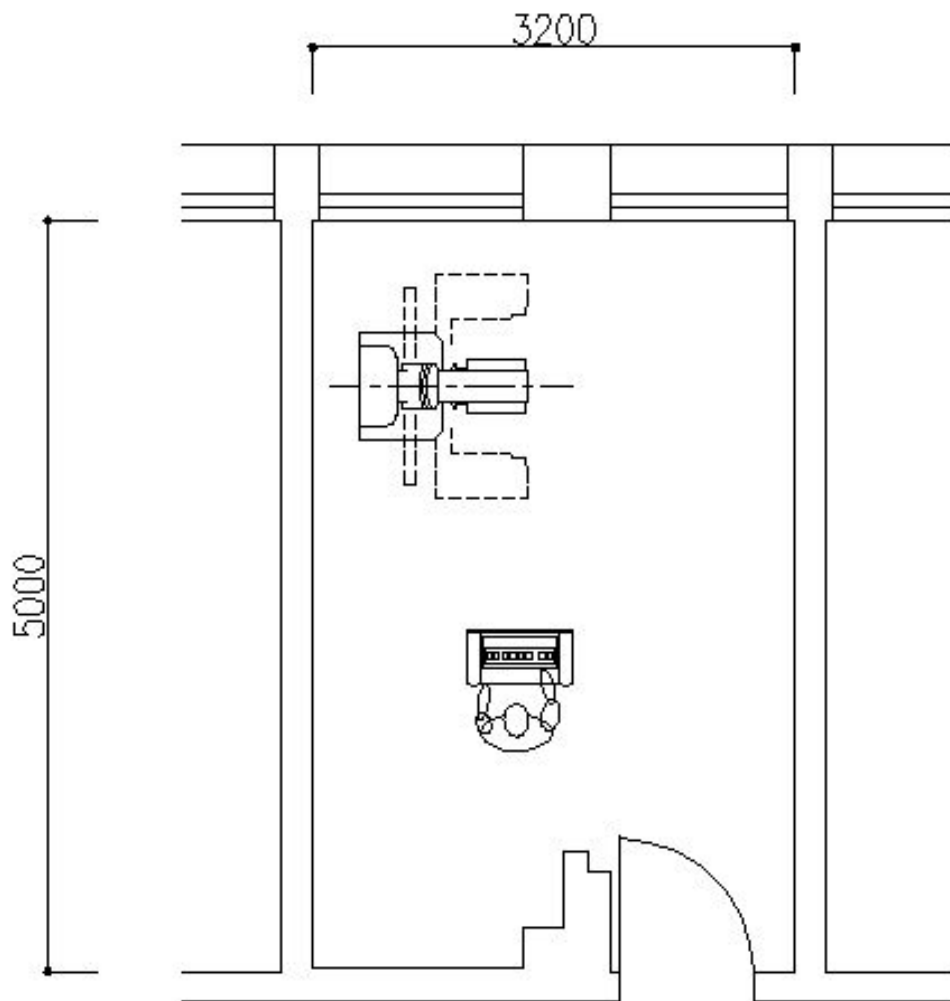
(1) Installation Plan	
• Mammography (Area)	Existing mammography room (18.7 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new mammography
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install partition, shading
• Approx Costs for Renovation Works	Euro 2,860 (RSD 270,000)



Site No.: HC-12	Health Centre Zajecar	C.H.: 4,250 mm
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No. 10

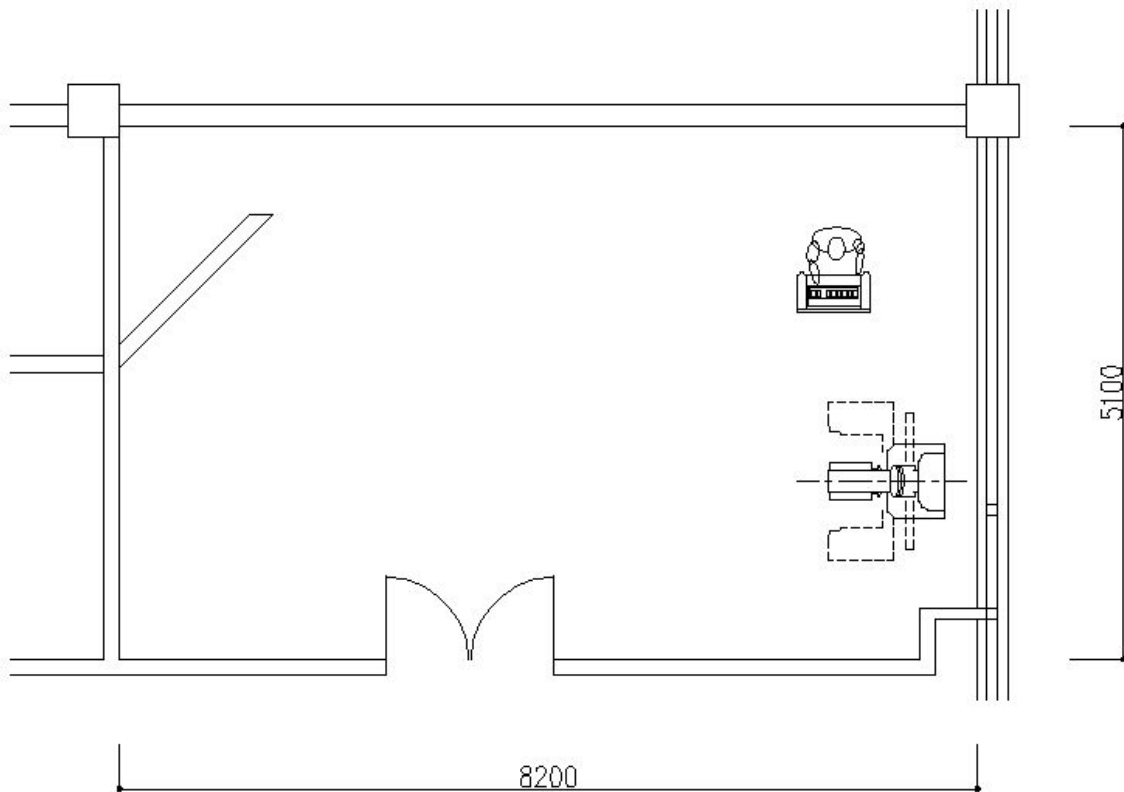
(1) Installation Plan	
• Mammography (Area)	Doctors room (16.0 m ²)
• CR System	Doctors room
• Dry Imager	Doctors room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 6,500 (RSD 613,000)



Site: HC-13	Health Center Uzice	C.H.: 2,900 mm
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No. 11

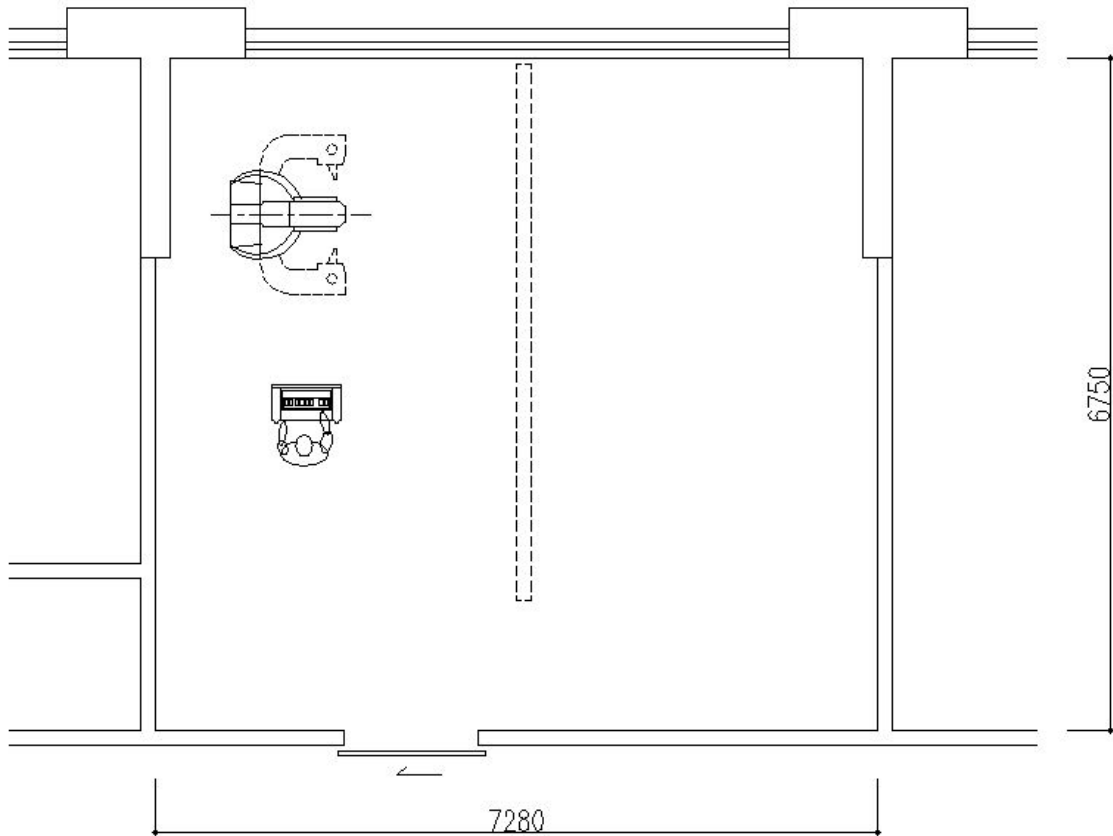
(1) Installation Plan	
• Mammography (Area)	Existing old X-ray machine room (41.8 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Non
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site: HC-15	General Hospital Gornji Milanovac	C.H.: 2,900 mm
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No. 12

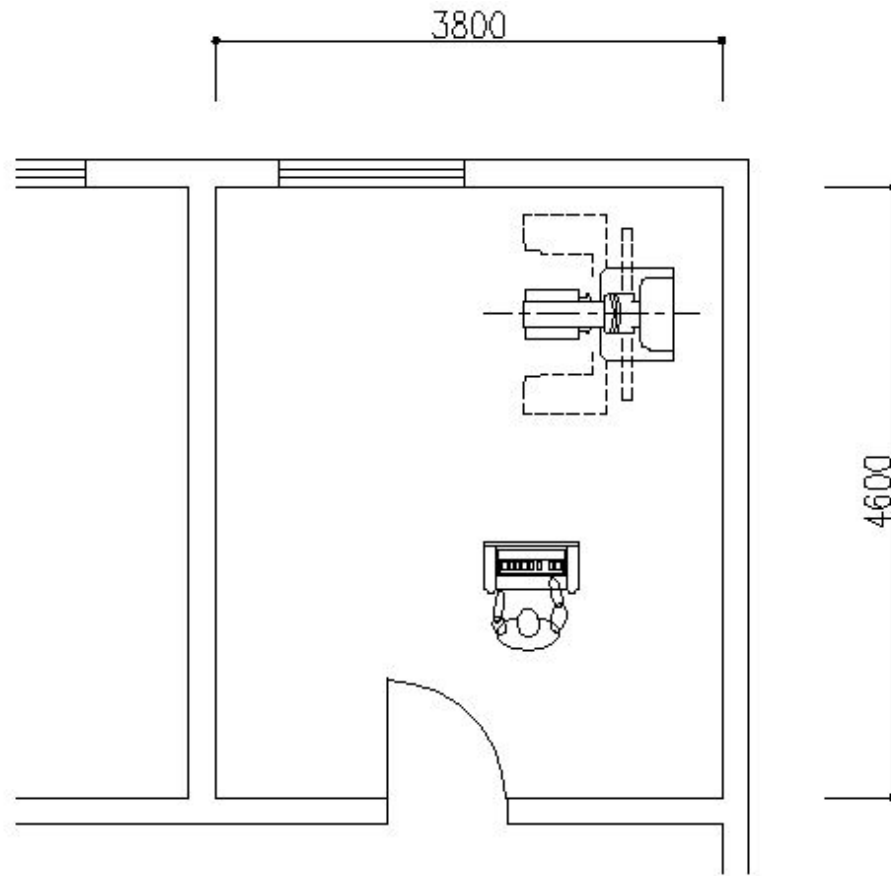
(1) Installation Plan	
• Mammography (Area)	Ultrasound diagnosis room (49.1 m ²)
• CR System	Ultrasound diagnosis room
• Dry Imager	Ultrasound diagnosis room
• X-ray Film Viewer	X-ray film reading room
(2) Existing mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new mammography.
(3) Items to be down by Serbian side	
• mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install partition, shading
• Approx Costs for Renovation Works	Euro 3,150 (RSD 297,000)



Site: HC-16	Health Centre Kraljevo	C.H.: 2,730 mm
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No. 13

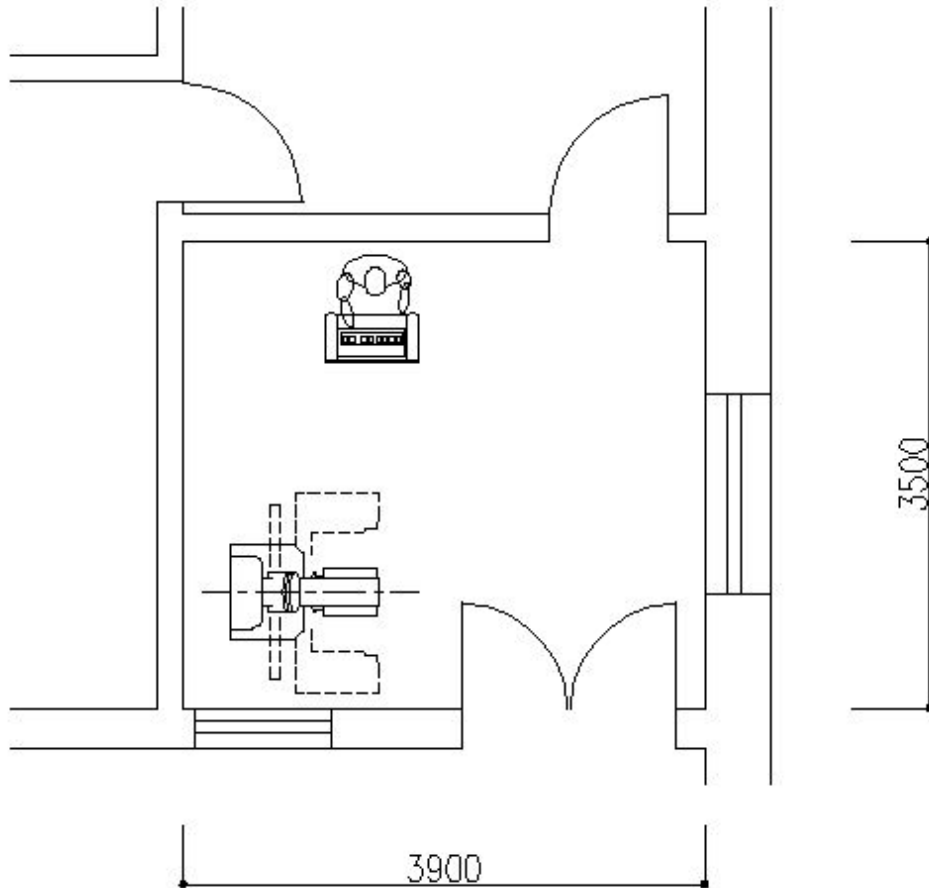
(1) Installation Plan	
• Mammography (Area)	Doctors room (17.5 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new mammography
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 5,500 (RSD 519,000)



Site: HC-17	Health Center Krusevac	C.H.: 2,900 mm
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No. 14

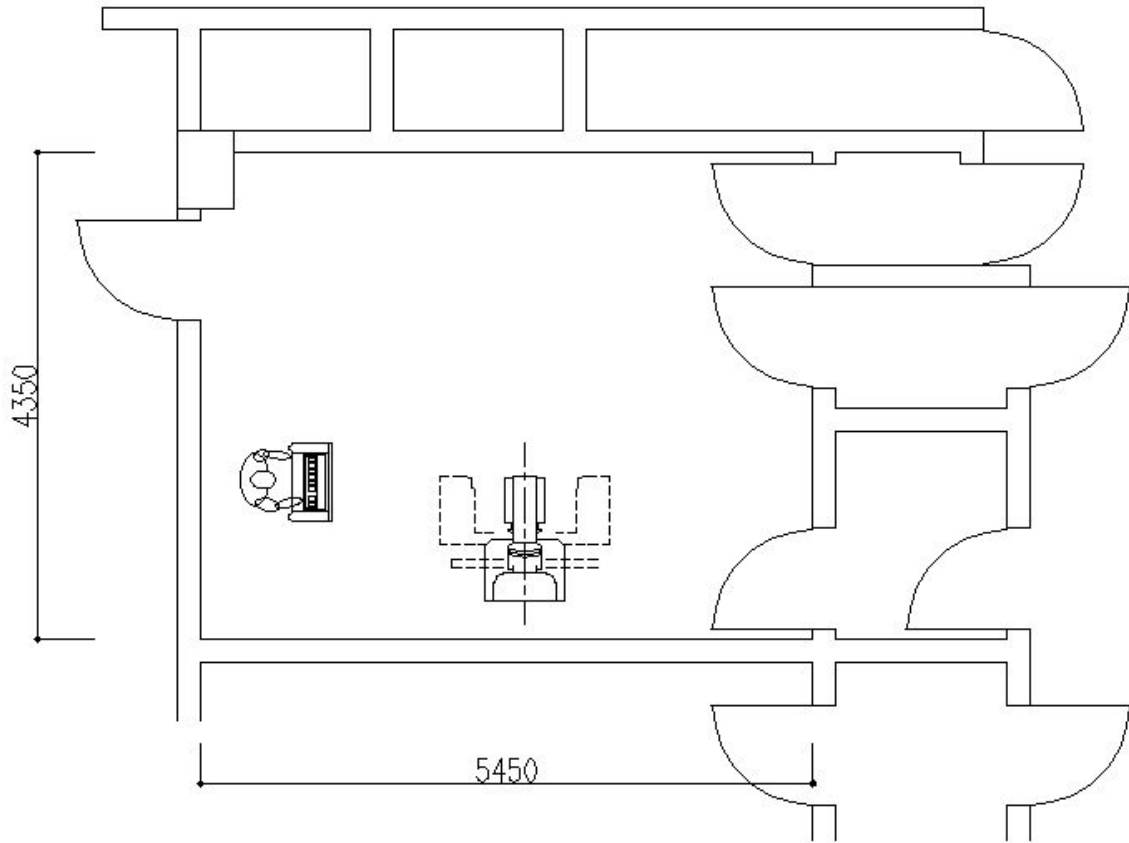
(1) Installation Plan	
• Mammography (Area)	Reception of X-ray dept. (13.7 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 3,480 (RSD 328,000)



Site: HC-18	Health Centre Aleksinac	C.H.: 3,930 mm
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No. 15

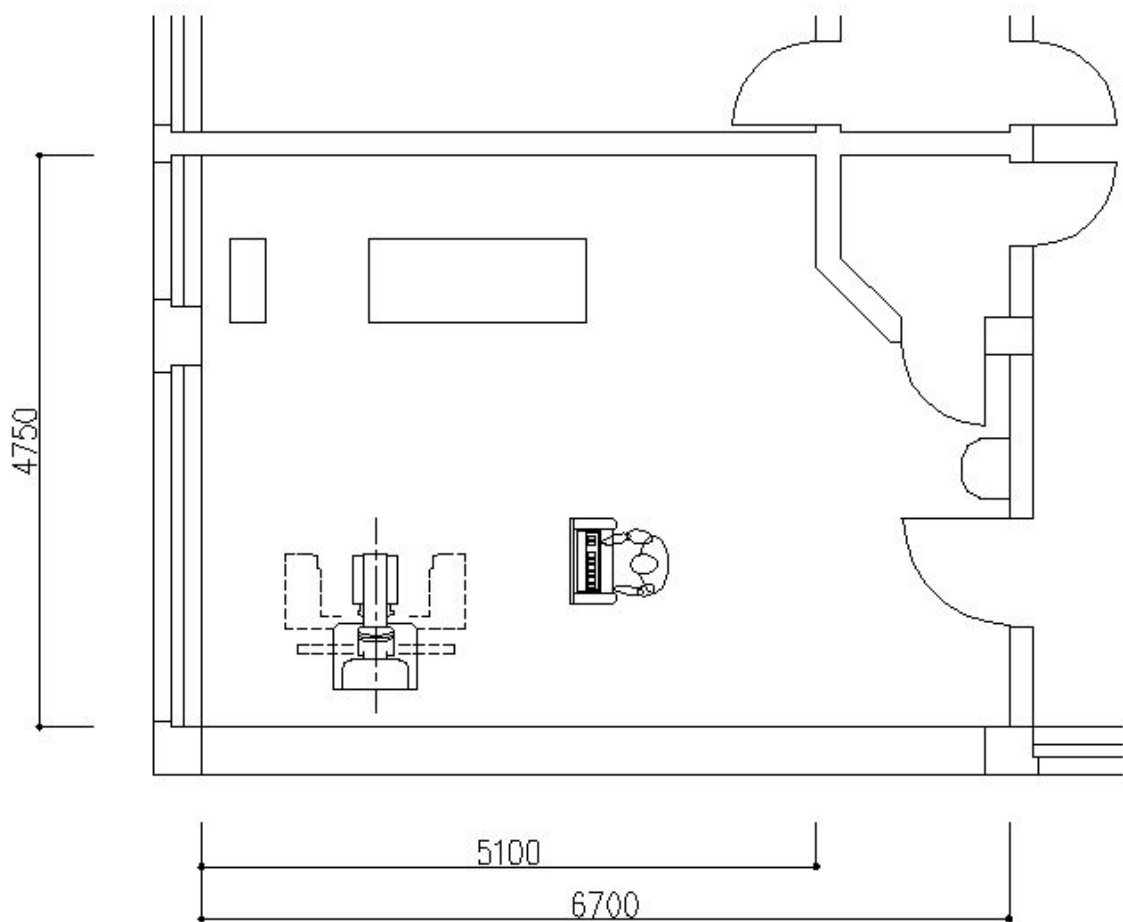
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (23.7 m ²)
• CR System	Existing X-ray machine room
• Dry Imager	Existing X-ray machine room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new mammography.
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, etc
• X-ray Film Reading Room	Install partition, shading
• Approx Costs for Renovation Works	Euro 1,420 (RSD 134,000)



Site: HC-19	Health Centre Piroć	C.H.: 3,290 mm
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No. 16

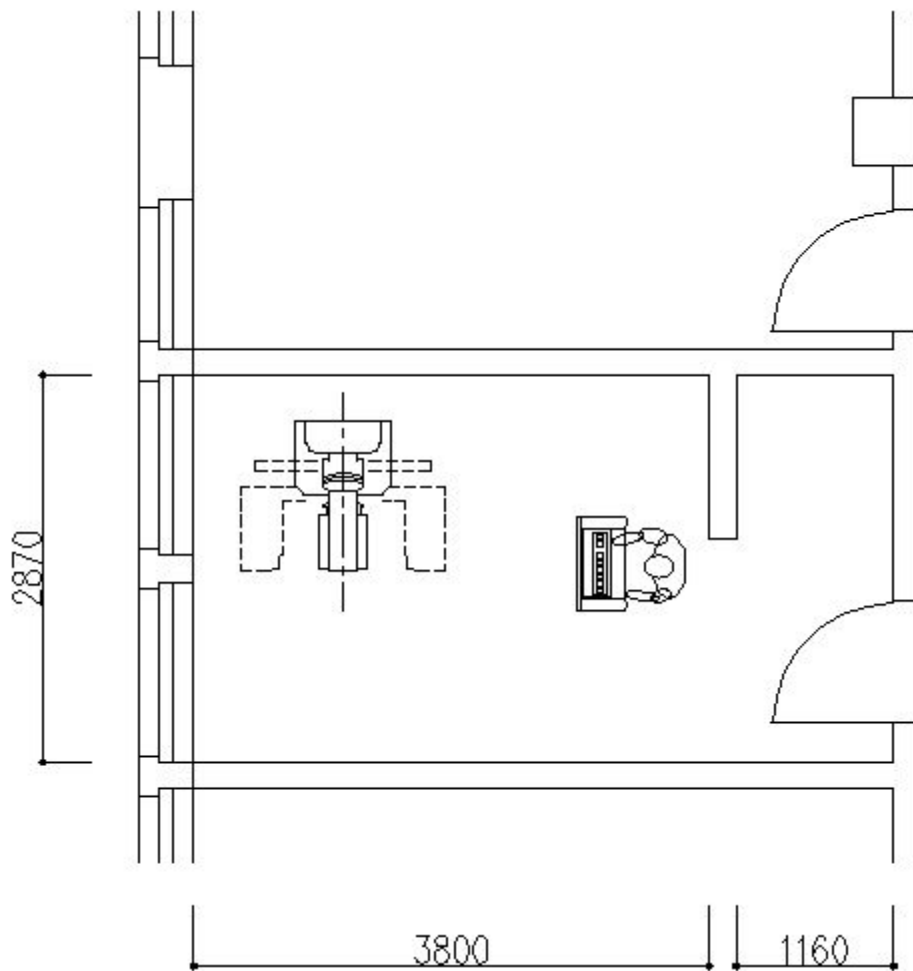
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (31.8 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes (Install at the ZD as an annex)
• Usage of Existing Mammography	It uses with a new mammography.
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 500 (RSD 47,000)



Site: HC-20	General Hospital Leskovac	C.H.: 3,200 mm
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No. 17

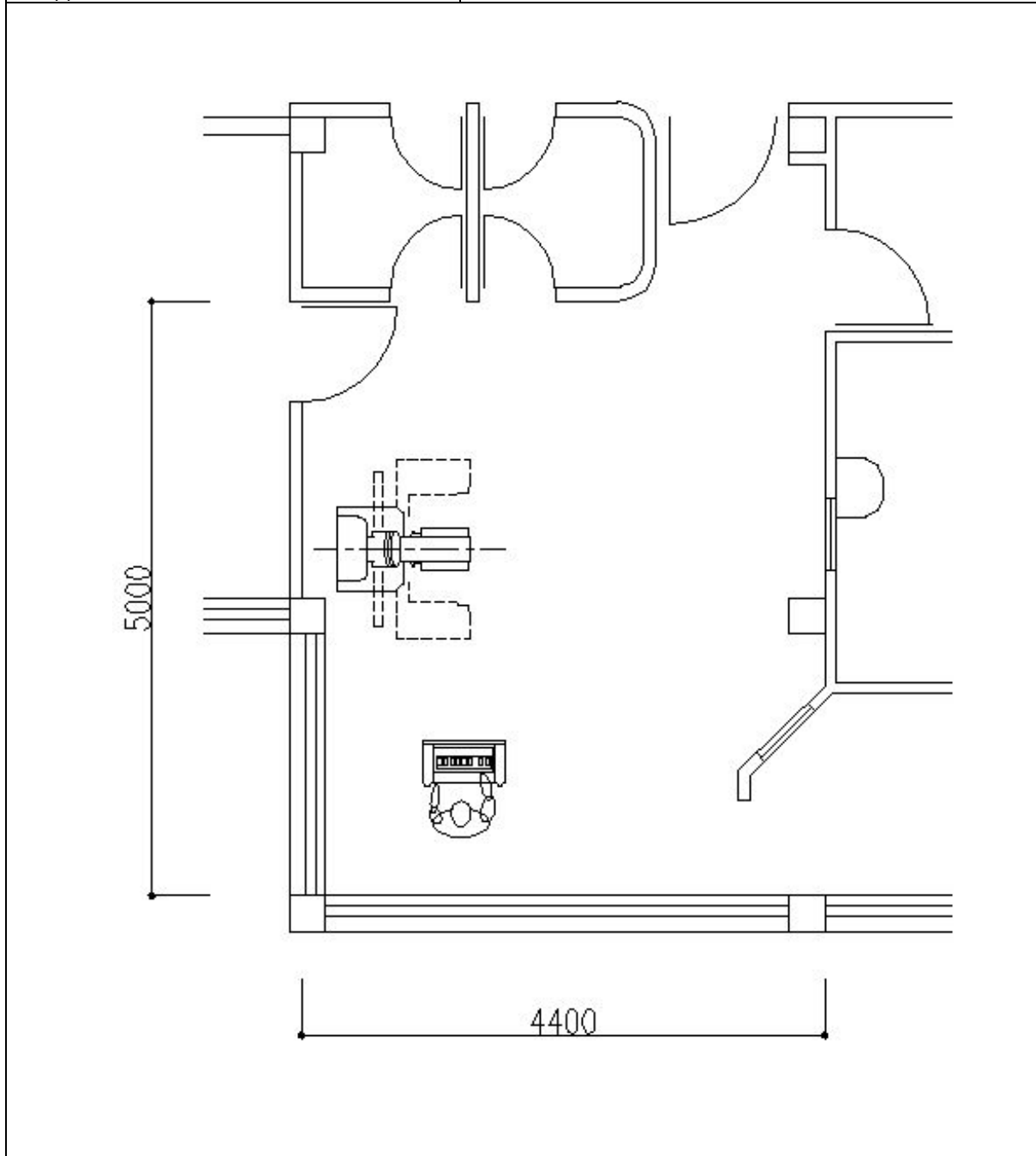
(1) Installation Plan	
• Mammography (Area)	New room for mammography (14.2 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new mammography.
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 1,020 (RSD 96,000)



Site: HC-22	General Hospital Sremska Mitrovica	C.H.: 2,920 mm
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No. 18

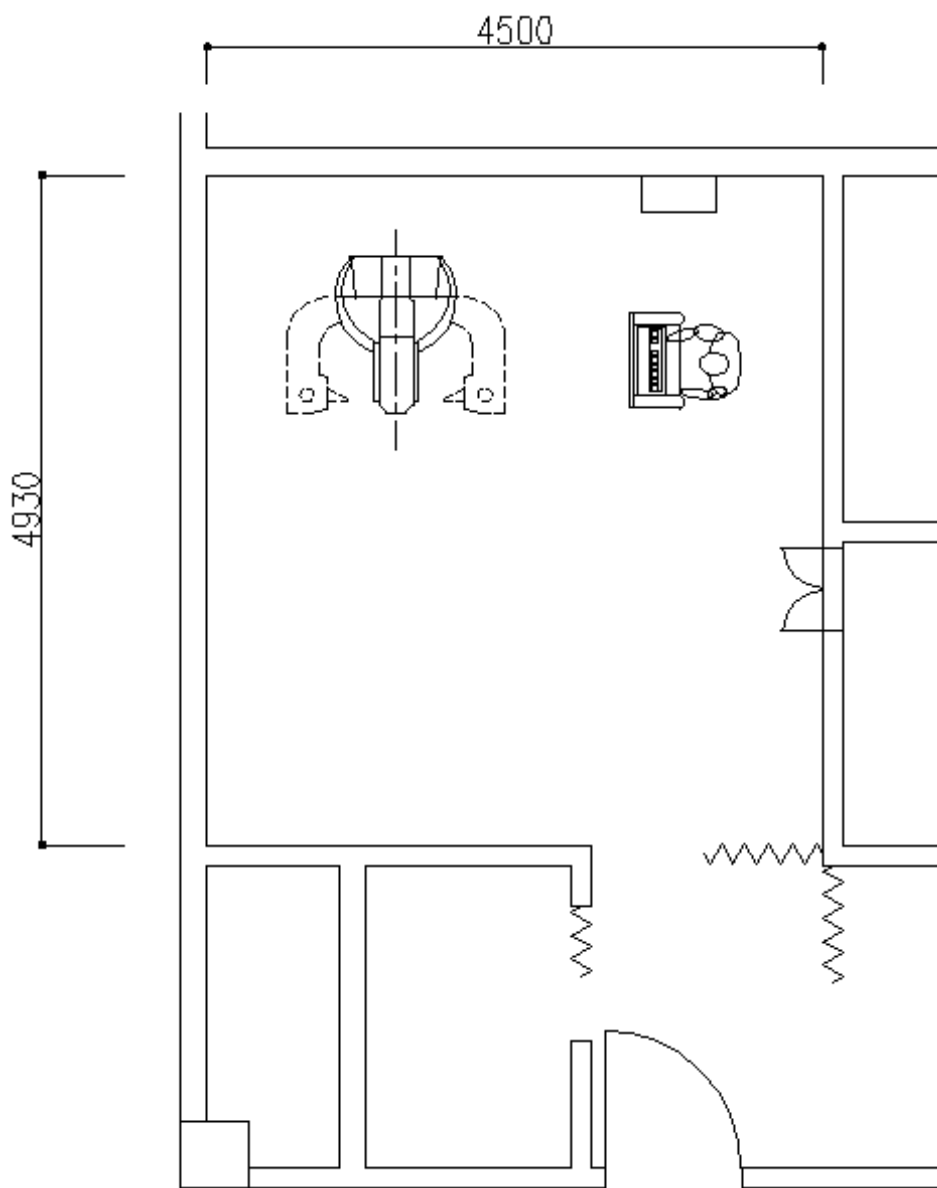
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (22.0 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing old X-ray machine
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site: PHC-02	Dom Zdravlja Novi Becej	C.H.: 2,700 mm
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No. 19

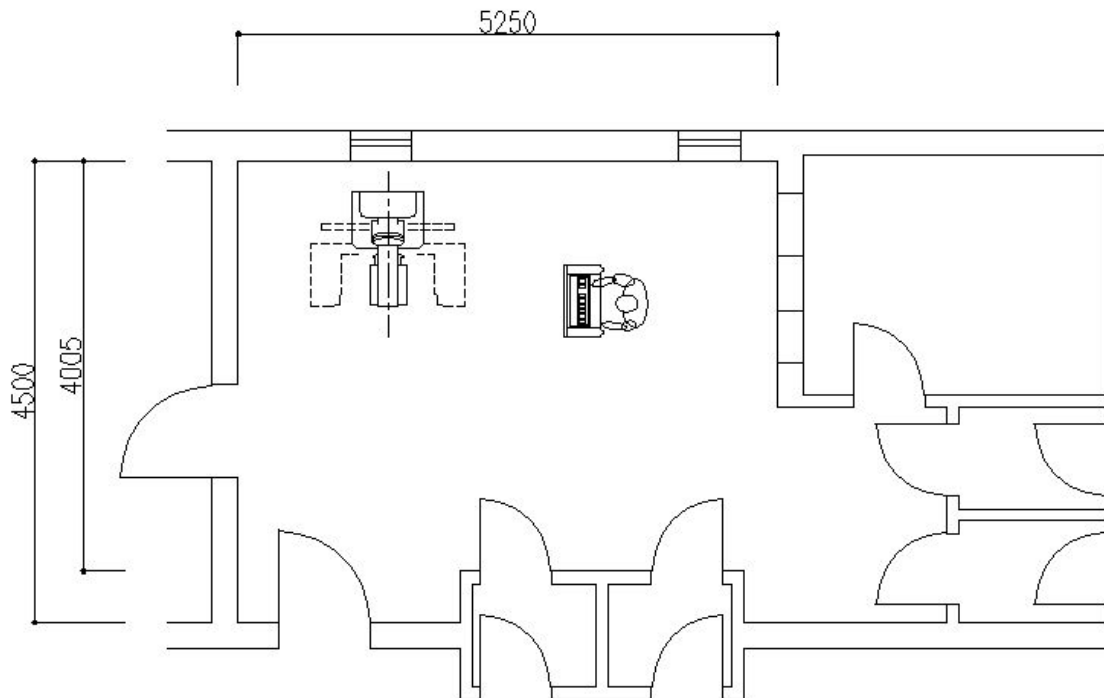
(1) Installation Plan	
• Mammography (Area)	Doctors room (21.0 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with a new mammography.
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply box, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 2,370 (RSD 223,000)



Site: PHC-04	Dom Zdravlja Novi Sad	C.H.: 3,170 mm
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No. 20

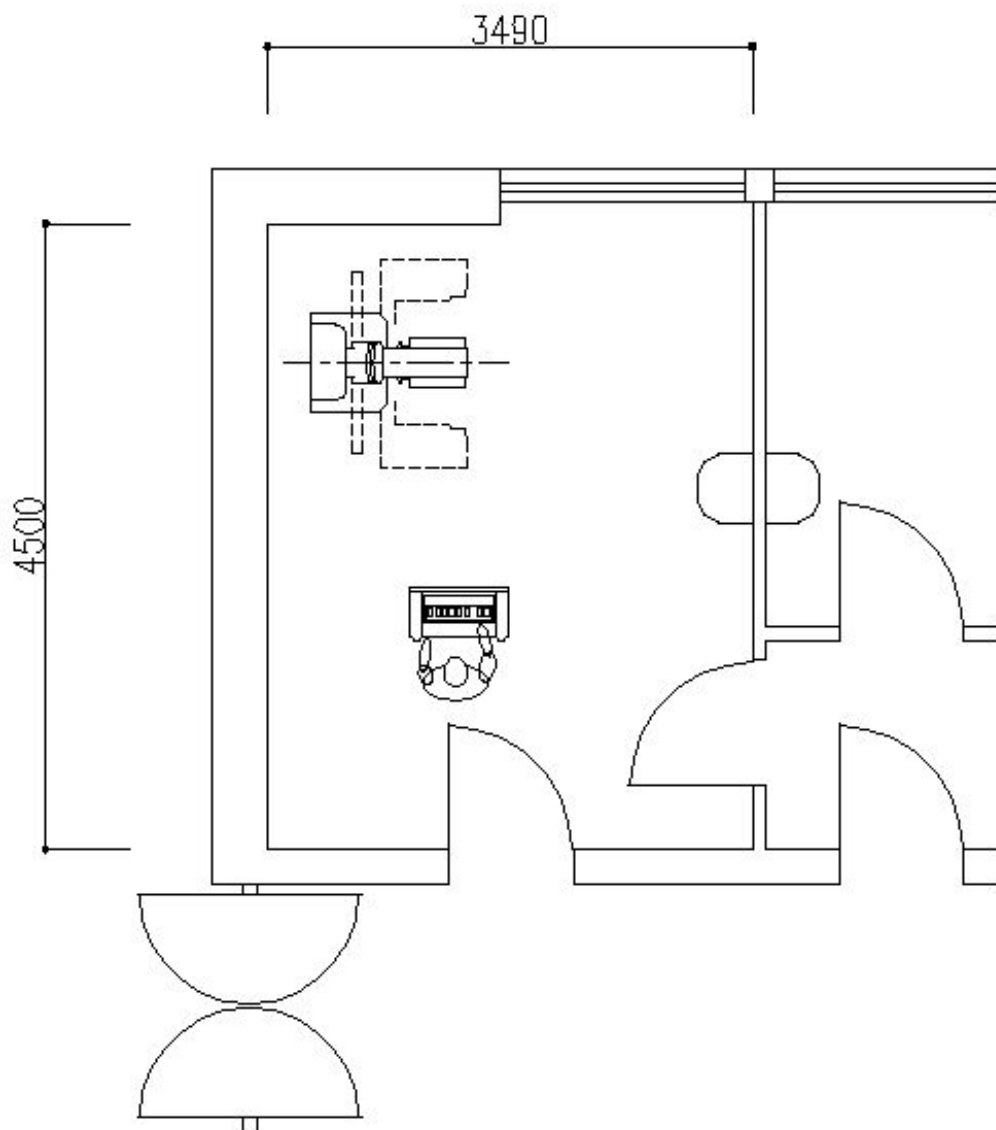
(1) Installation Plan	
• Mammography (Area)	Existing X-ray room (21.0 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing old X-ray machine
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site: PHC-06	Dom Zdravlja Bogatic	C.H.: 3,050 mm
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No. 21

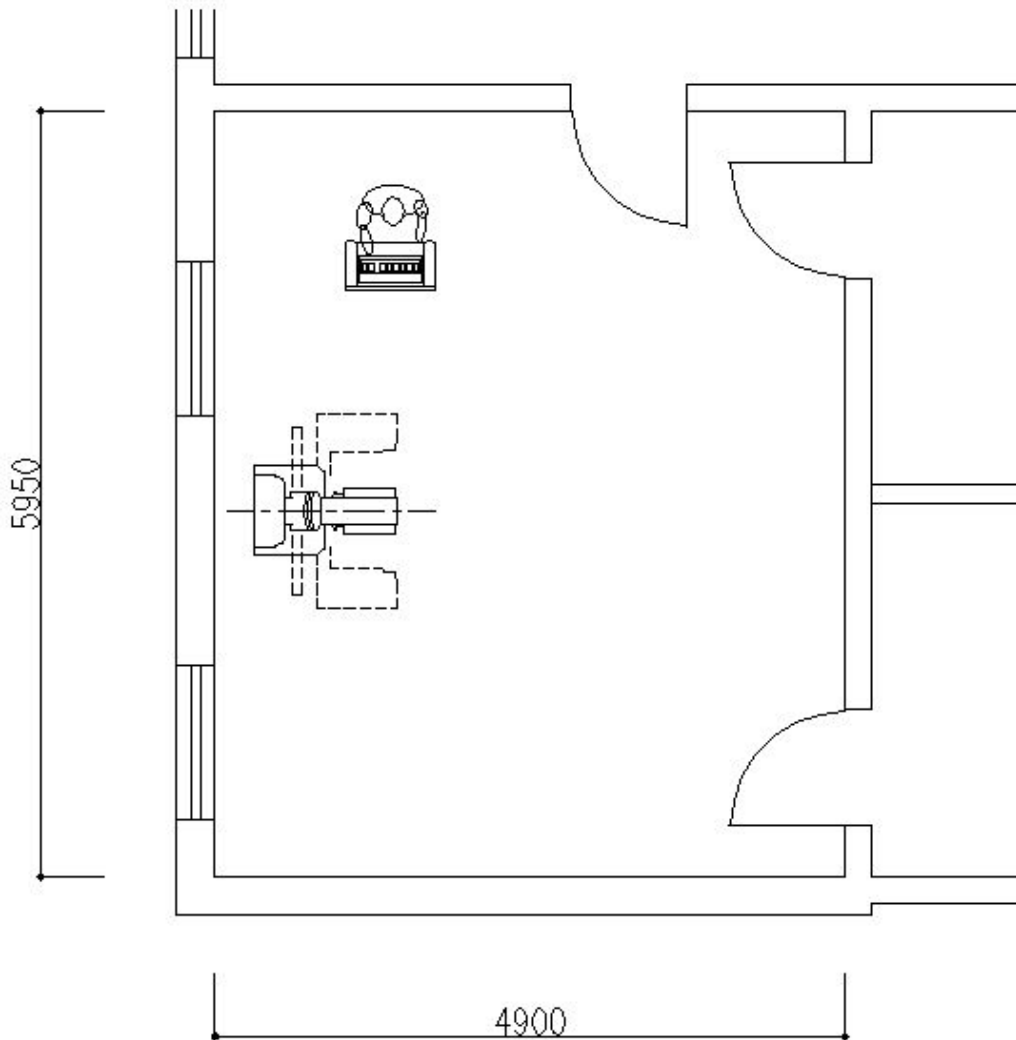
(1) Installation Plan	
• Mammography (Area)	New room for mammography (15.7 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Aprox Costs for Renovation Works	Euro 640 (RSD 60,000)



Site: PHC-07	Dom Zdravlja Kragujevac	C.H.: 3,160 mm
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No. 22

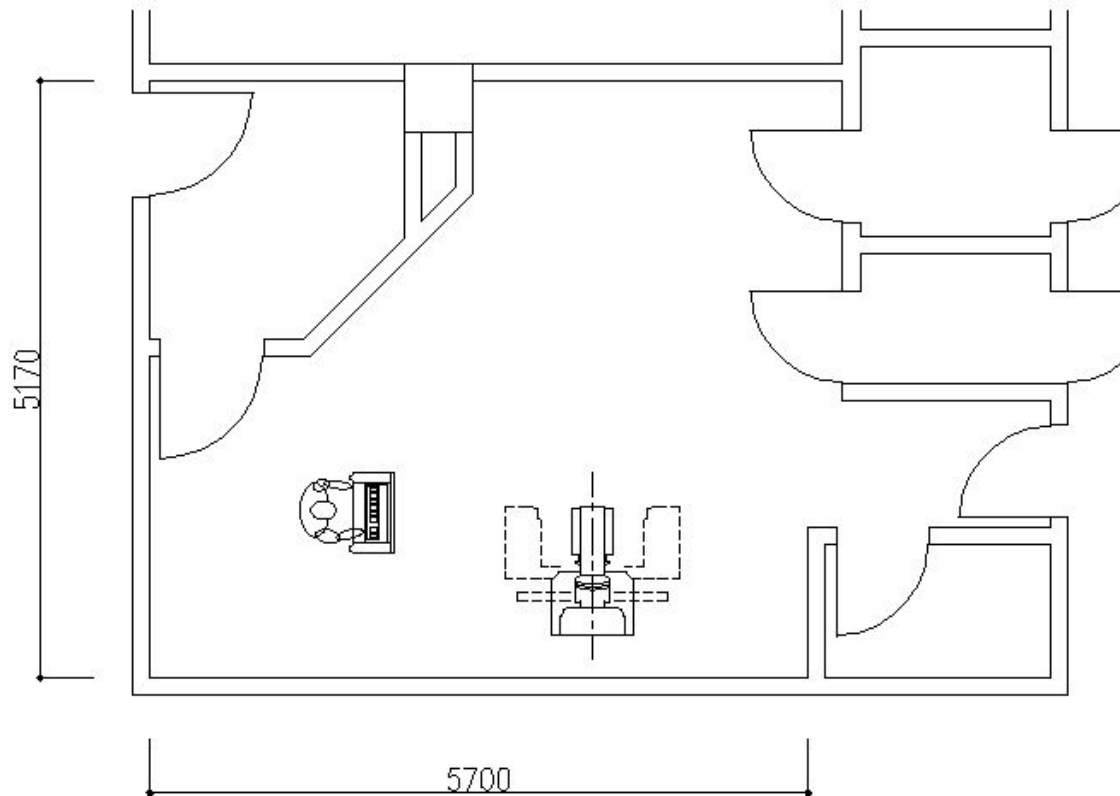
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (29.2 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Non
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site: PHC-08	Dom Zdravlja Trstenik	C.H.: 3,200 mm
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No. 23

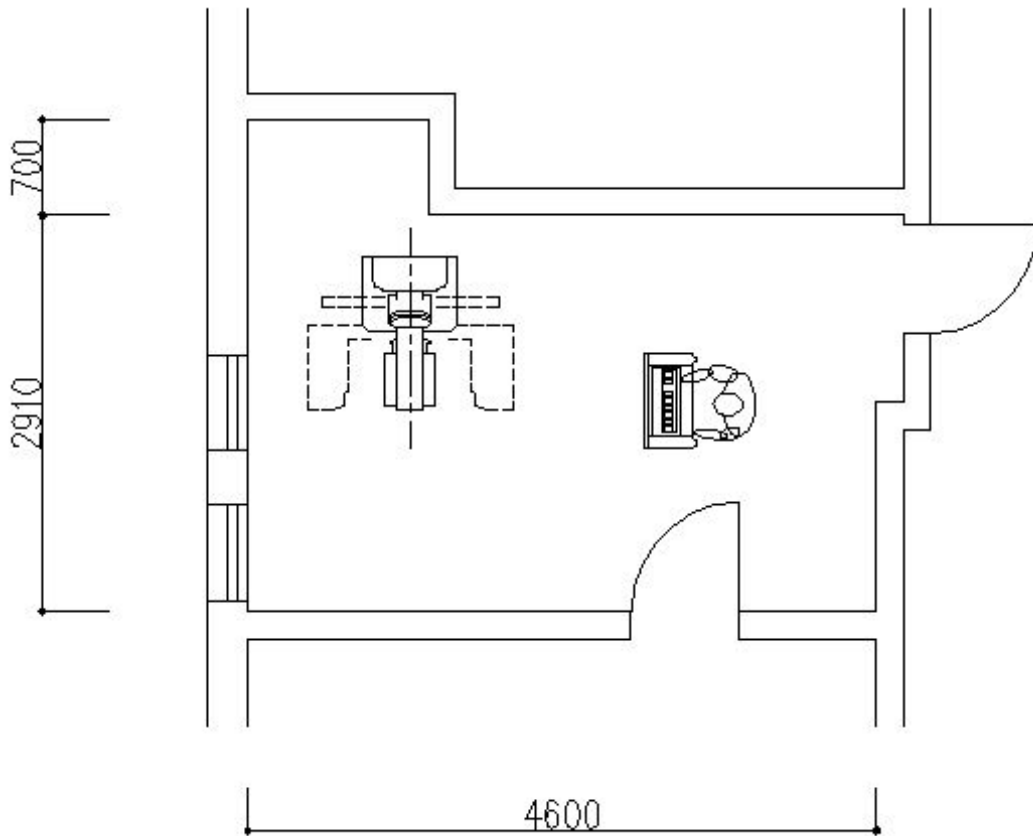
(1) Installation Plan	
• mammography (Area)	Existing X-ray machine room (29.5 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing machine, install power supply breaker
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 510 (RSD 48,000)



Site: PHC-09	Dom Zdravlja Nis	C.H.: 3,180 mm
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No. 24

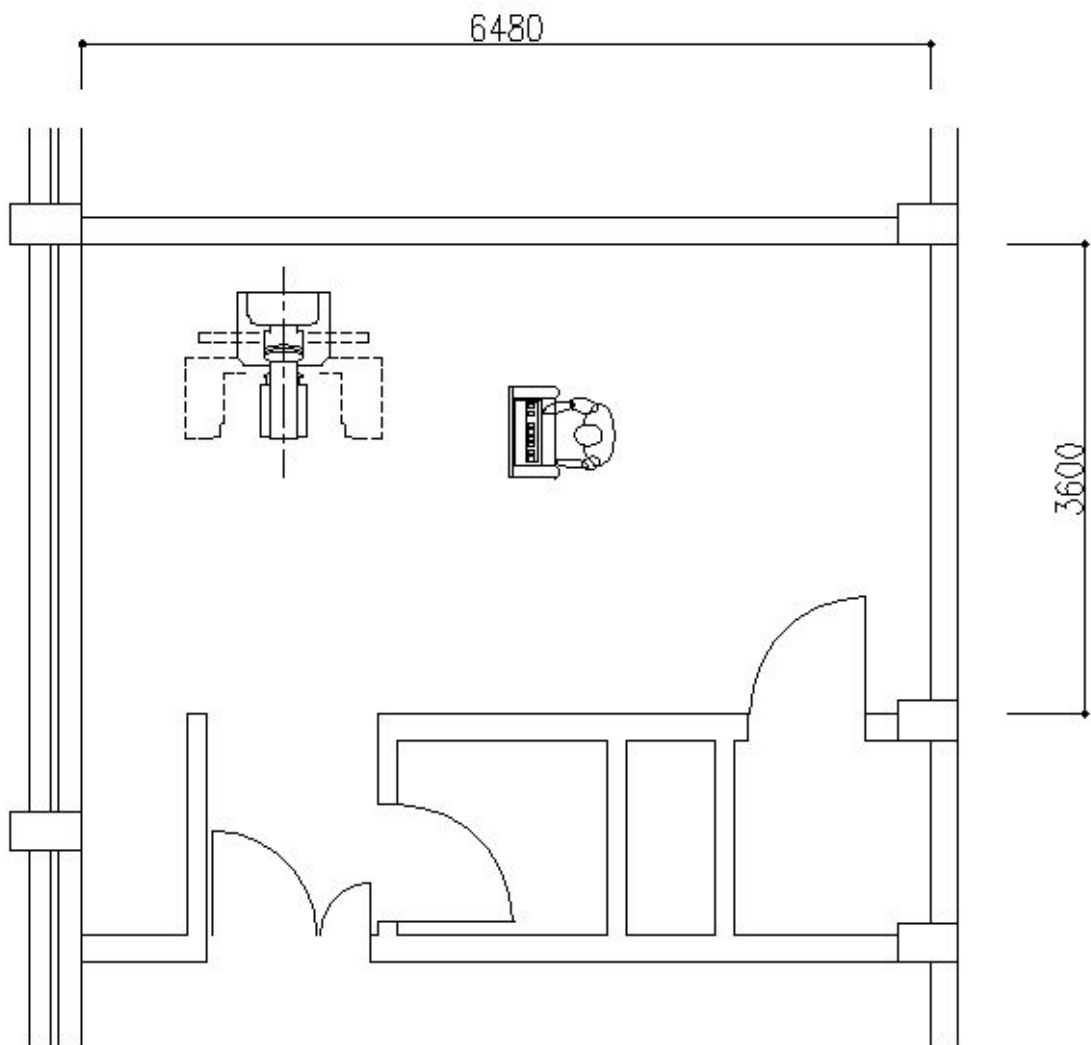
(1) Installation Plan	
• Mammography (Area)	Doctors room (13.4 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 4,800 (RSD 453,000)



Site: PHC-10	Dom Zdravlja Bujanovac	C.H.: 2,800 mm
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No. 25

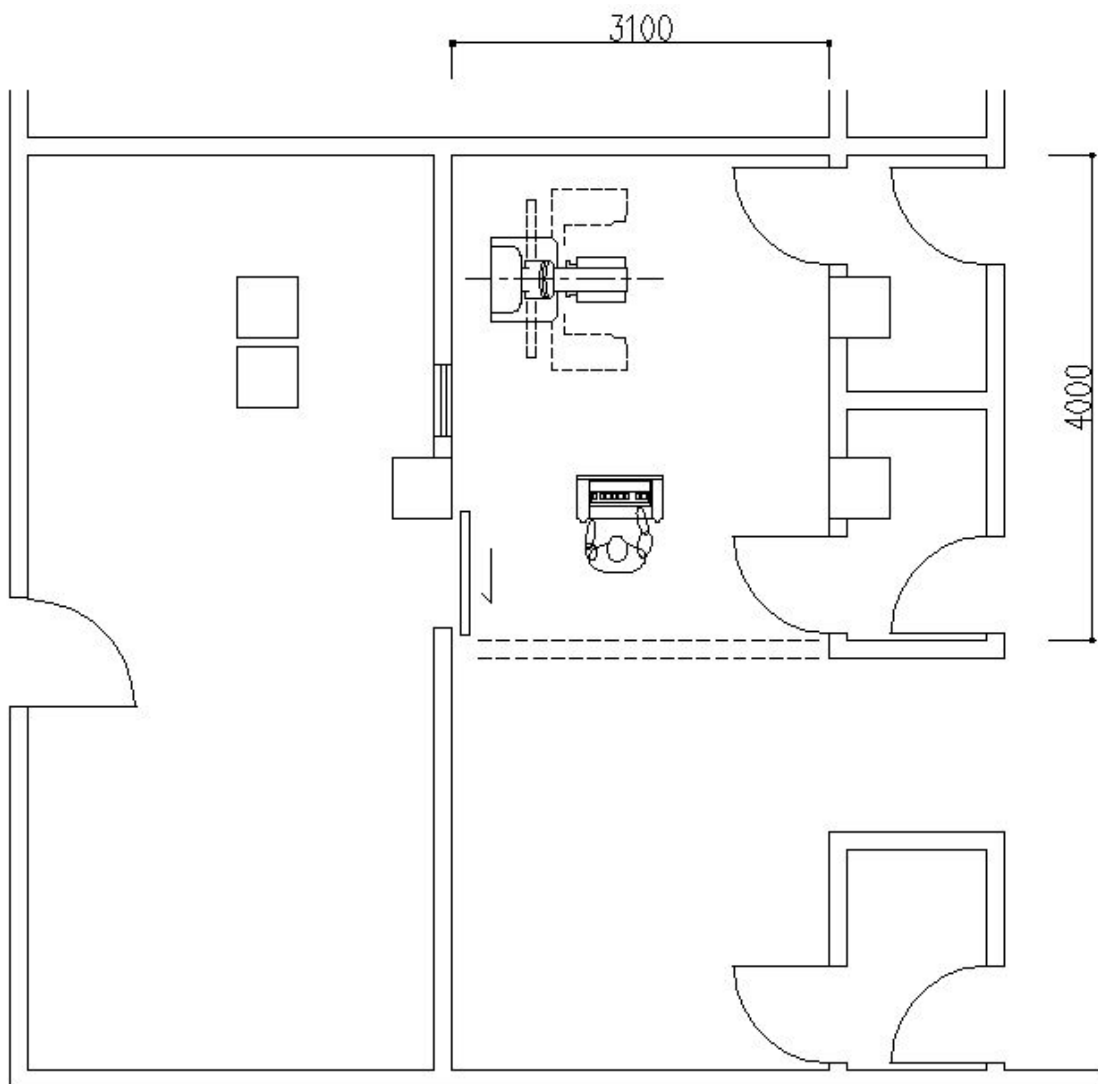
(1) Installation Plan	
• Mammography (Area)	New room for mammography (23.3 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 1,840 (RSD 173,000)



Site: PHC-11	Dom Zdravlja Grocka	C.H.: 2,750 mm
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No. 26

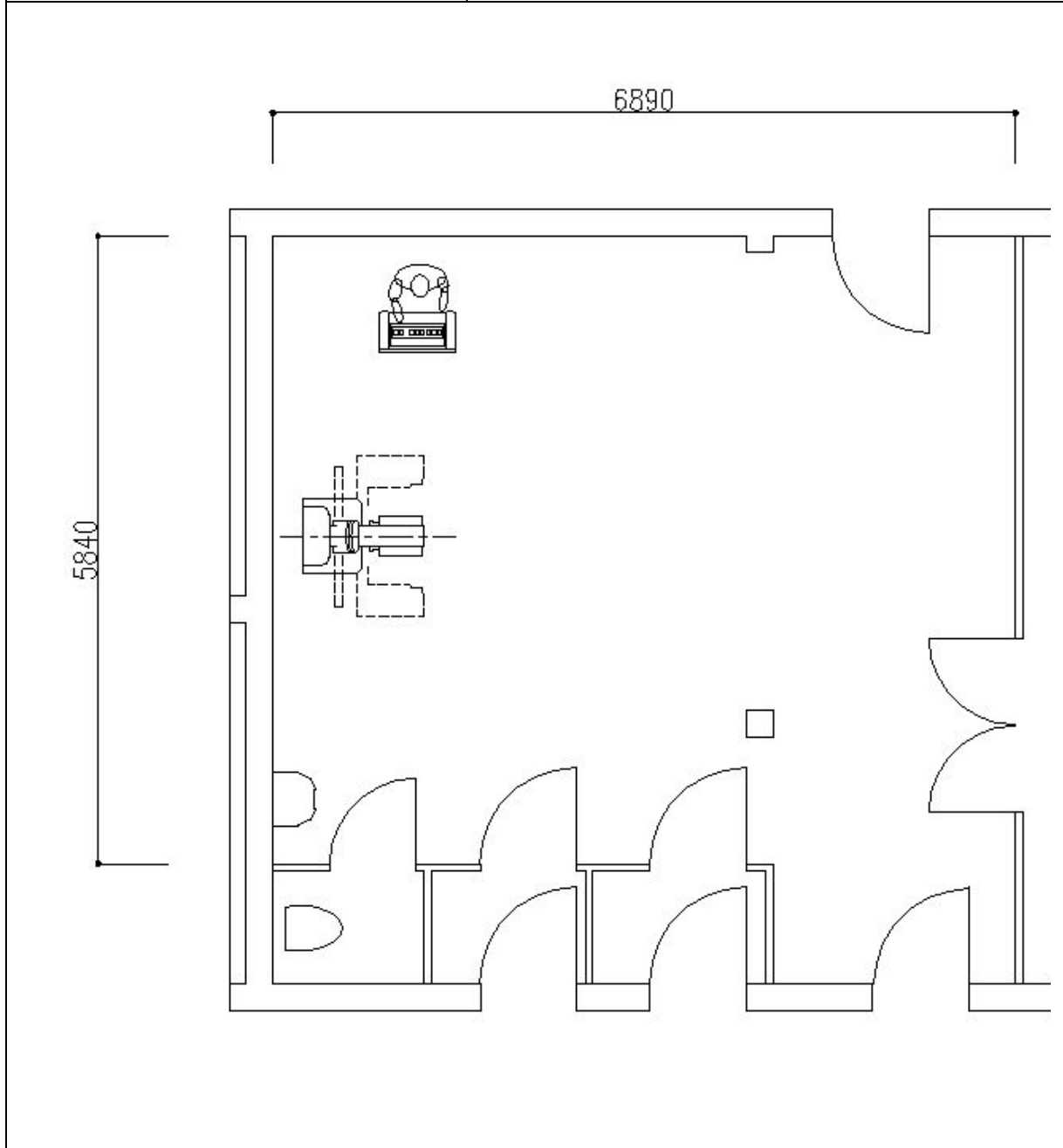
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (12.4 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 4,000 (RSD 377,000)



Site: PHC-12	Dom Zdravlja Zemun	C.H.: 2,880 mm
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No. 27

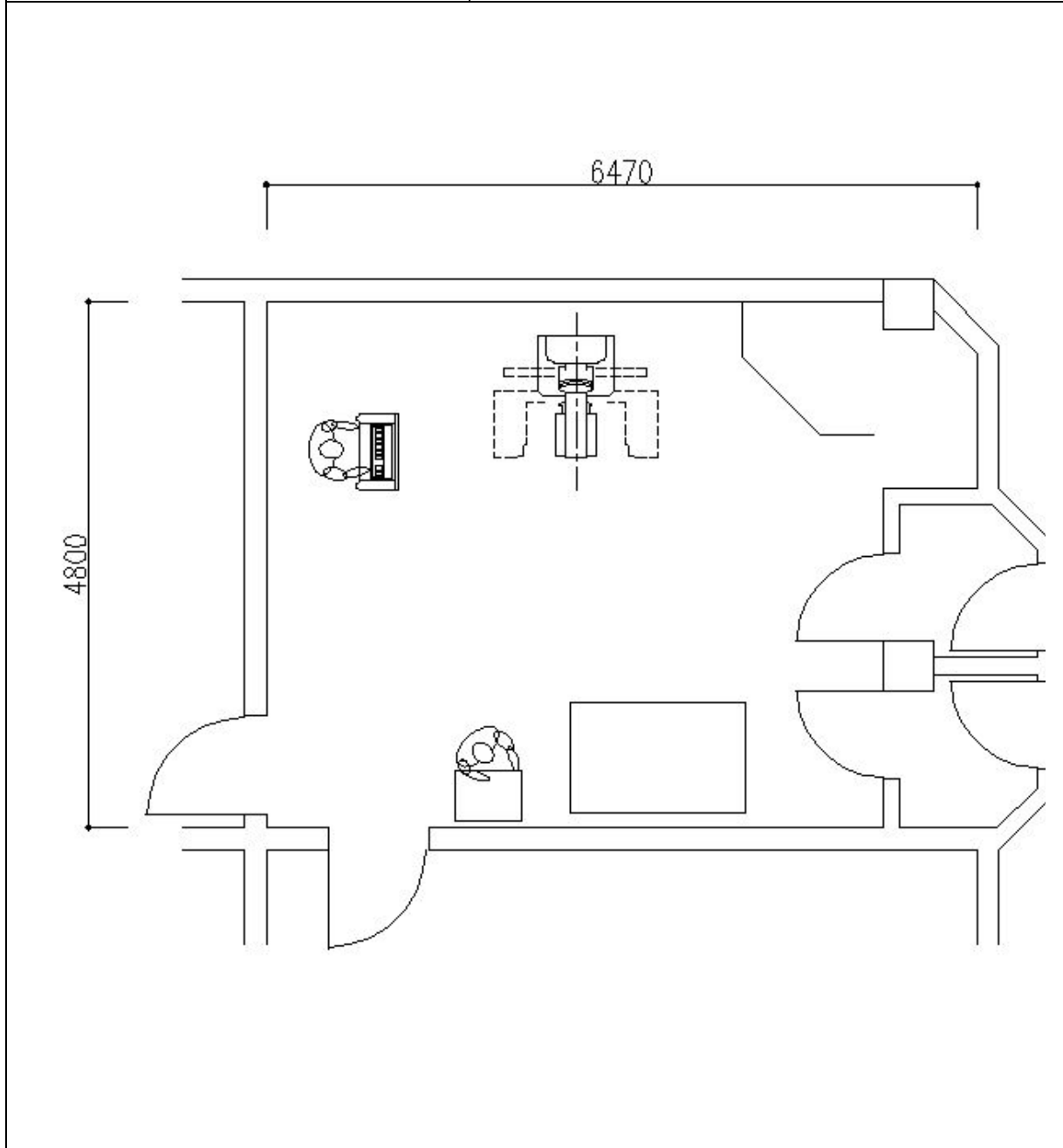
(1) Installation Plan	
• Mammography (Area)	Existing X-ray machine room (40.5 m ²)
• CR System	X-ray film reading room
• X-ray Film Processor	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Yes
• Usage of Existing Mammography	It uses with anew mammography.
(3) Items to be down by Serbian side	
• Mammography Installation Room	Remove existing old X-ray machine
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Non



Site: PHC-13	Dom Zdravlja Lazarevac	C.H.: 2,800 mm
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No. 28

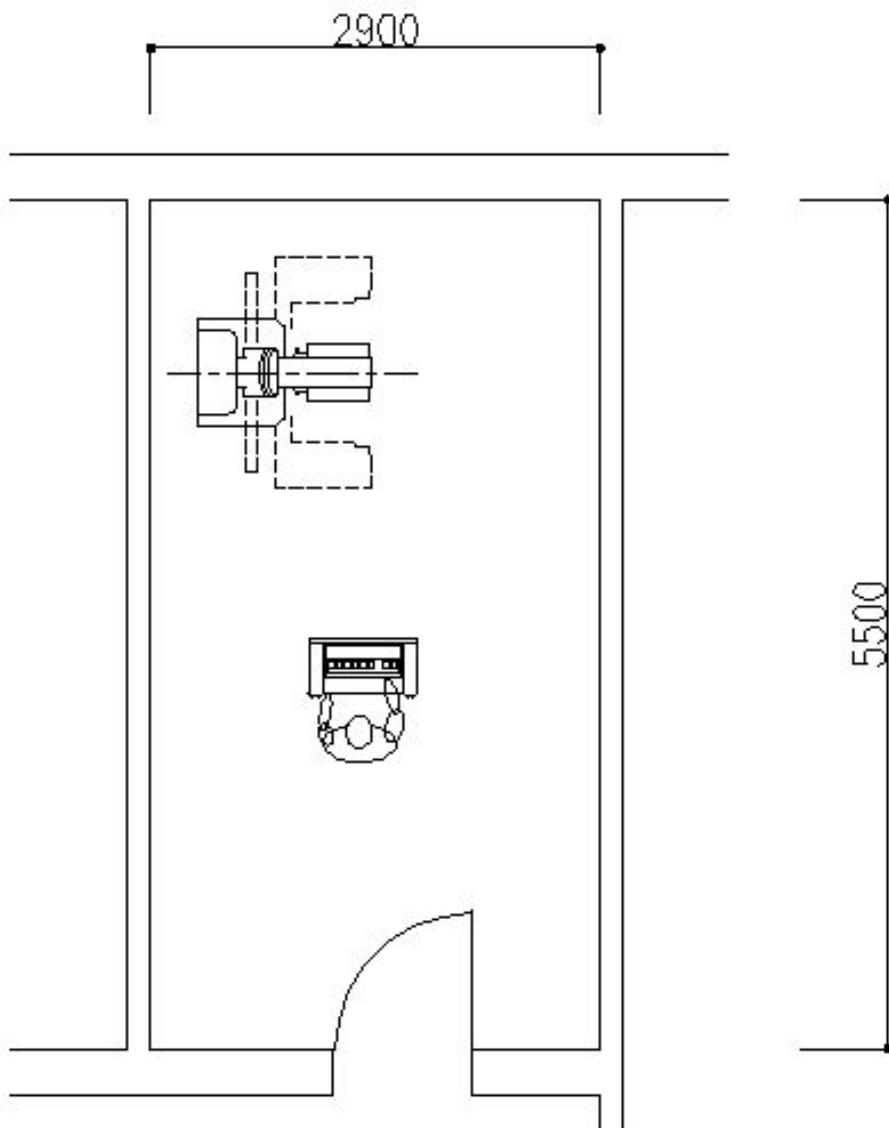
(1) Installation Plan	
• Mammography (Area)	Existing born density measuring room (31.1 m ²)
• CR System	X-ray film reading room
• X-ray Film Processor	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 180 (RSD 17,000)



Site: PHC-14	Dom Zdravlja Novi Beograd	C.H.: 3,800 mm
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No. 29

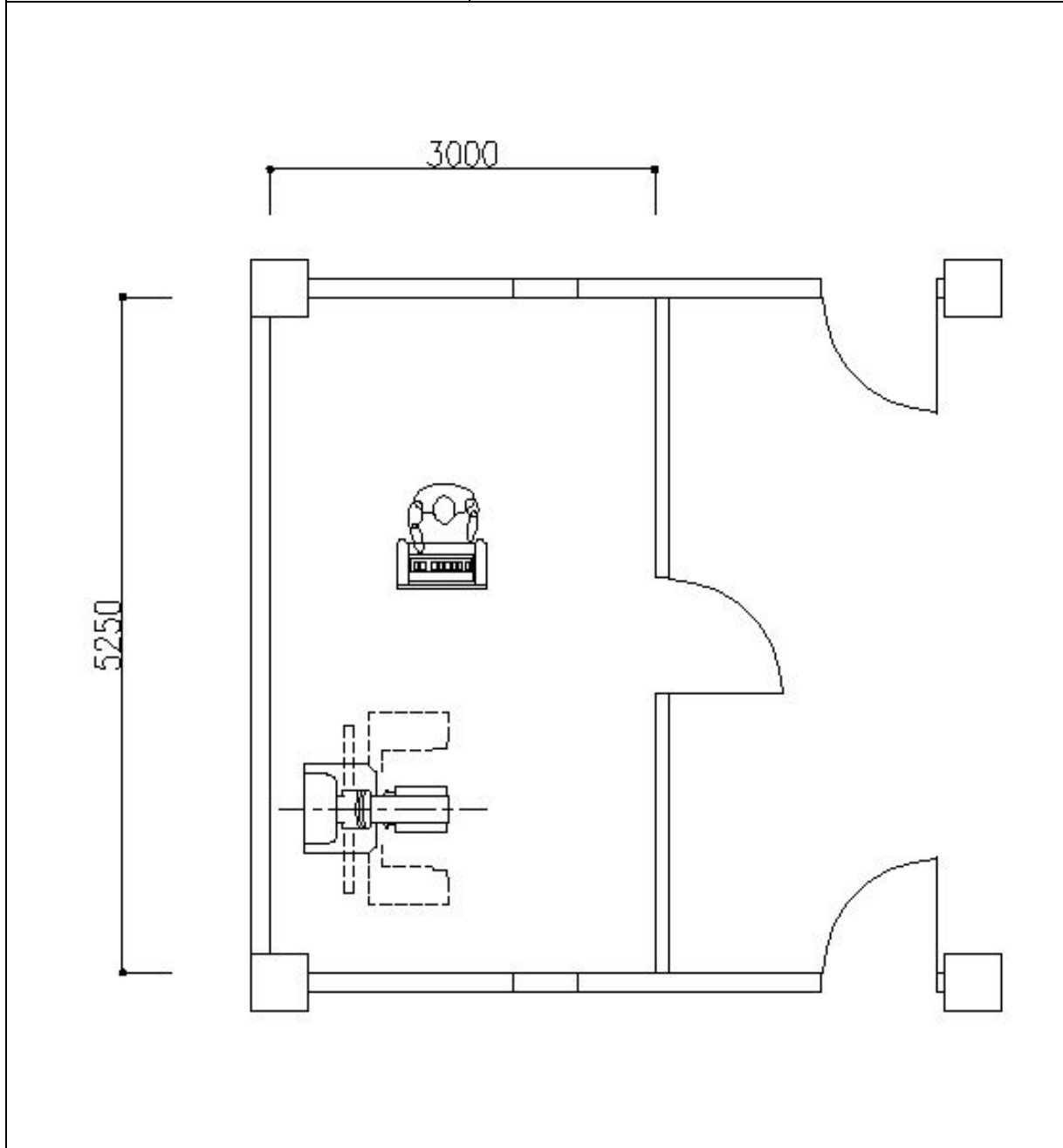
(1) Installation Plan	
• Mammography (Area)	Doctors room (16.0 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 6,500 (RSD 613,000)



Site: PHC-15	Dom Zdravlja Obrenovac	C.H.: 2,800 mm
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No. 30

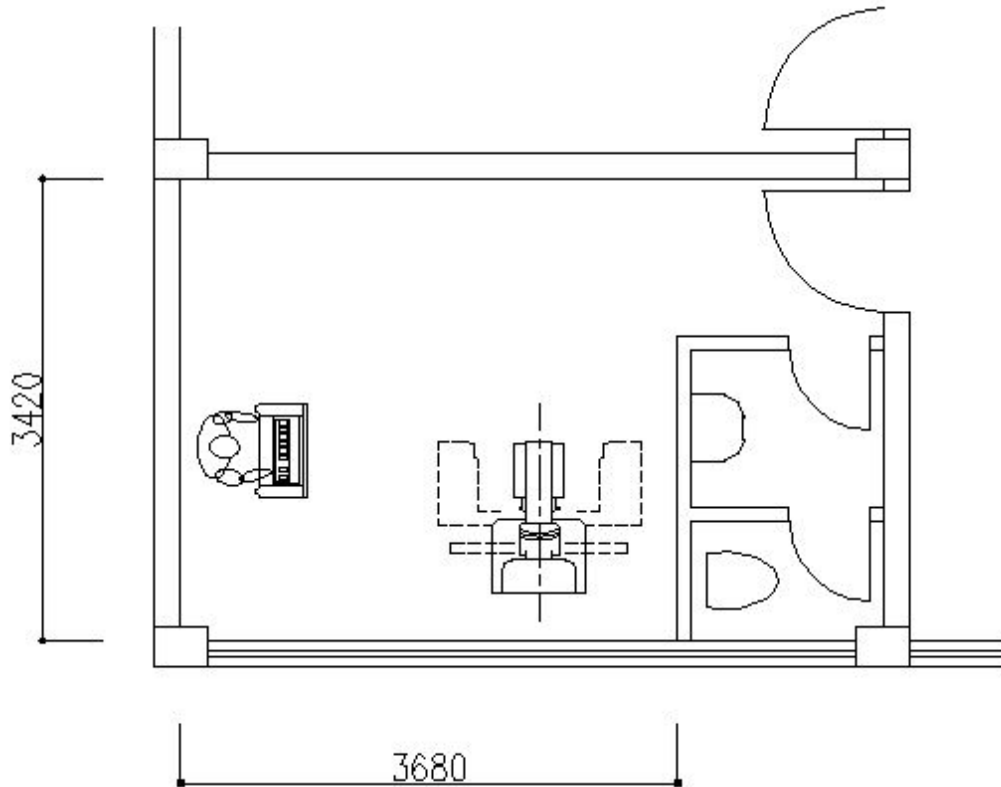
(1) Installation Plan	
• Mammography (Area)	Doctors room (15.8 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 7,000 (RSD 660,000)



Site: PHC-16	Dom Zdravlja Palilula	C.H.: 3,000 mm
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No. 31

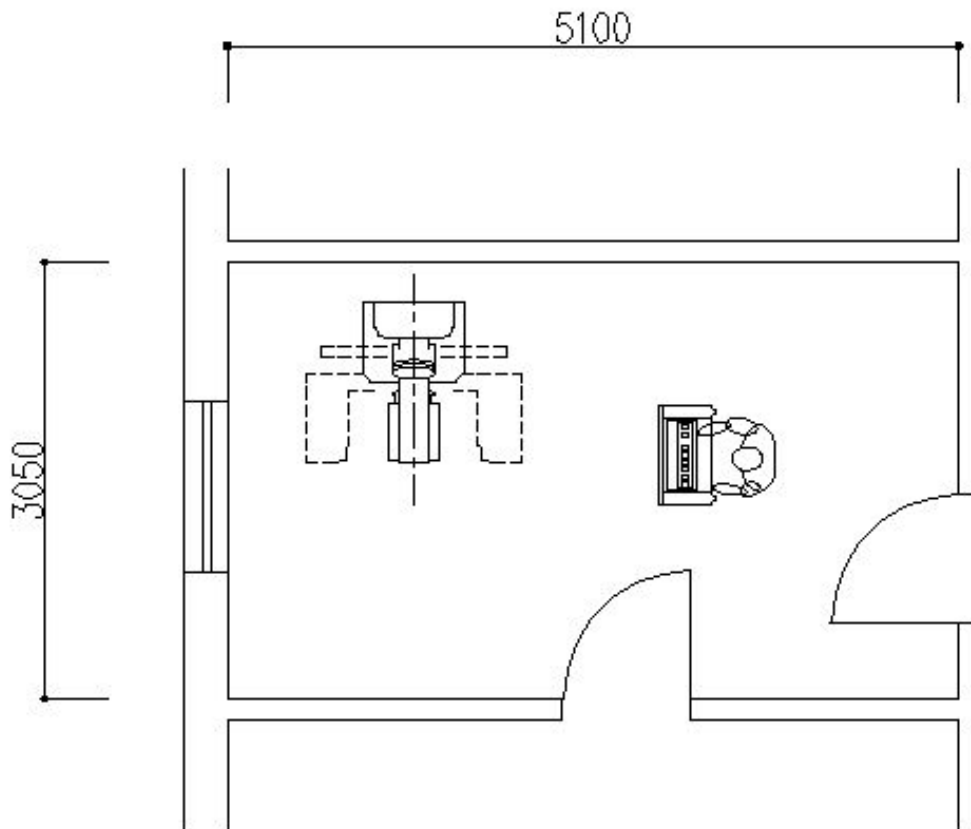
(1) Installation Plan	
• Mammography (Area)	Staff changing room (12.6 m ²)
• X-ray Film Processor	X-ray film processing room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 2,500 (RSD 236,000)



Site: PHC-17	Dom Zdravlja Rakovica	C.H.: 3,220 mm
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No. 32

(1) Installation Plan	
• Mammography (Area)	Doctors room (15.6 m ²)
• CR System	X-ray film reading room
• Dry Imager	X-ray film reading room
• X-ray Film Viewer	X-ray film reading room
(2) Existing Mammography	
• There is or not	Non
• Usage of Existing Mammography	-
(3) Items to be down by Serbian side	
• Mammography Installation Room	Install power supply breaker, lead protection, etc
• X-ray Film Reading Room	Install shading
• Approx Costs for Renovation Works	Euro 5,000 (RSD 471,000)



Site: PHC-18	Dom Zdravlja Stari Grad	C.H.: 3,000 mm
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2-2-4 Implementation Plan

2-2-4-1 Implementation Policy

(1) Standards Implementing Procedure of the Project

Implementation of the Project will be decided through the review of this report by relevant governmental agencies in Japan and an approval by the Japanese Cabinet. After the approval of the Project, the Exchange of Notes (E/N) will be signed between Japanese and Serbian governments and the Grant Agreement (G/A) on the Project will be signed between implementation agency of Serbia and JICA. The Project will be implemented after completing these processes. In accordance with the Japan's Grant Aid scheme, a consultant and an equipment supplier will conclude agreement/contract(s) with the government of Serbia to implement the Project. Approvals by JICA will be required for these agreement/contract(s).

(2) Project Implementation System

The Project will be implemented under the supervision of the MoH of Serbia. The Bureau of Public Health and Health Promotion of the MoH will be the party to the agreement for the consulting services, equipment procurement contract, Banking Arrangement (B/A), and other such agreements to be concluded for the Project. The Bureau of Drug and Medical Equipment of the MoH will be in charge of arranging discussions and coordinating technical details and other matters concerning the specific contents of the Project.

(3) Consultant

After execution of the E/N and G/A between the two governments, the MoH of Serbia shall conclude an agreement for consulting services with the Japanese consultant firm, with regard to the detail design (including tender and tender-related works) and the supervision of the procurement / installation. Said agreement is subject to verify of JICA. For the smooth implementation of the Project, it is important to conclude the agreement immediately after the signing of the E/N and G/A. Upon conclusion of the agreement and JICA verifies the said agreement, the consultant will immediately start services based on this report with the MoH of Serbia and related authorities concerned, then, prepare tender documents, obtain the approval, conduct the tender, and supervise the procurement / installation works following to the scope of works under the tender conditions.

(4) Equipment Supplier

The equipment supplier to procure and install the equipment for the Project shall be selected through competitive tendering. As a rule for the tender, the bidder offering the lowest price as well as technical consistencies shall be successful bidder. The MoH of Serbia will

then conclude the supply contract with the successful bidder of the equipment and obtain the verification of JICA. The equipment supplier shall complete required works within the period specified in the contract, and hand over the equipment to the MoH of Serbia after conducting final inspection at the Project sites.

2-2-4-2 Implementation Conditions

In implementing this Project, special attention should be paid to the following points:

(1) Minimizing the Interruption of Clinical Services Medical during Installation Period

The health facilities covered by the Project need to continue their routine clinical services during the installation, operation & maintenance training periods, the periods in which the services are interrupted must be minimized. In order to minimize the interruption, the procurement process of the equipment should be strictly supervised, and the installation and operation & maintenance training, as well as final inspection schedule should be formulated through discussion in advance and strictly observed with those related to the target health facilities. In addition, certain measures should be taken to ensure the safety of patients and clinical staff at Project sites.

(2) Transportation / Delivery Route

For sea transportation from Europe and the U.S.A. as well as Japan, the cargo may be unloaded at Copper Port, Slovenia or at Bar Port, Montenegro. Then, the cargo will pass temporary customs clearance at a cargo unloaded port and undergo formal customs clearance at the bonded warehouse in Belgrade, the capital of Serbia. Equipment shipped from western and northern Europe will be transported by sea via the Mediterranean Sea while shipments from Germany and East European countries relatively near Serbia will use the land route.

As points of concern, the shipping documents, such as Pro-forma invoice shall be submitted to the MoH immediately after shipments, so that the procedure of tax exemption and customs clearance will be conducted in advance.

2-2-4-3 Scope of Works

The Grant Aid Project will be implemented by mutual cooperation between the Governments of Japan and Serbia in accordance with the Grant Aid System. Both countries will share the works in the Project as described below.

(1) Works to be carried out by the government of Japan

- 1) Cost of equipment procurement under the Project,
- 2) Cost of marine transportation and cost of inland transportation to the each health facility in Serbia,
- 3) Cost of equipment installation and setup, and
- 4) Cost of test run, give instructions / training for operation and maintenance and final inspection for all the procured equipment.

(2) Works to be carried out by the Government of Serbia

- 1) Presentation of information and data necessary for equipment installation and setup,
- 2) Remove old equipment and prepare the rooms to which new equipment is to be installed,
- 3) Prepare facility infrastructure, such as electricity, water supply / drainage, and radiation shields at the installation sites for the new equipment,
- 4) Provide places to unload the procured equipment,
- 5) Temporary storage spaces for the equipment until the installation, and
- 6) Secure delivery routes spaces especially for the equipment which is required to install in the facilities.

2-2-4-4 Consultant Supervision

Based on the Japanese Grant Aid scheme, the Japanese consultant shall conclude the agreement for consulting services with the MoH of Serbia, according to which the consultant will render detailed design (including tender and tender-related works) and perform procurement supervisory services. The purpose of consultant supervision is to make certain that the equipment supplier selected through public tender is properly carrying out its assigned obligations according to the contract concluded with the MoH of Zambia and to give guidance and make necessary adjustments from an objective viewpoint to ensure proper execution. The supervisory work consists of the following services.

(1) Assistance with tender procedure and contracting

To select a Japanese trading company to take charge of the equipment procurement /

installation, the consultant will prepare tender documents, announce the tender publicly, distribute the tender documents to bidders, accept and evaluate tenders offered, and give advice with regard to the contract to be concluded between the MoH of Serbia and the selected supplier.

(2) Instructions, advice, and coordination for the Supplier

The consultant will examine the procurement / installation plan and give instructions and advice to the supplier to make certain adjustments if necessary.

(3) Inspection and approval of related documents

The consultant will examine the equipment procurement / installation schedule and its management structure by staff concerned, technical documents related to the equipment, and other necessary documents to be submitted from the supplier, give advice as necessary, and approve the documents.

(4) Report on the progress of the works

The consultant will monitor the progress of actual work against the proposed plan, and report to the related parties in Japan and Serbia.

(5) Inspection and testing upon completion

Upon completion of the work, the consultant will attend the on site inspection and test-run of the equipment in order to confirm that the equipment is consistent with provisions of the contract. Final inspection report will be submitted to authorities concerned on the Serbian side.

2-2-4-5 Procurement Plan

In procuring the equipment for the Project, the following points should be noted:

(1) Country of origin of the planned equipment

The equipment for the Project will be procured from Japan, as well as certain third countries, such as the Federal Republic of Germany (Germany), the United State of America (USA), the Republic of Italy (Italy), French Republic (France), the Republic of Hungary (Hungary), and the Republic of Finland (Finland), etc. As third-country products, digital and analog mammography units, CR systems, Dry imagers, X-ray film processors and X-ray film viewers will be considered for the sustainable operation and maintenance of the equipment at the Project sites as well as fair competition on the public tender.

(2) Transportation period

The transportation period for the equipment procured from Japan, Europe and the USA will require about 35 to 45 days for marine transportation, and about 7 days for customs clearance and land transportation, making about 42 to 52 days in total.

2-2-4-6 Operational guidance plan

Equipment to be procured in the Project requires basic operation and maintenance skills. It will be necessary to train the clinical staff and maintenance staff in operation and troubleshooting of the equipment during the period of installation, adjustment, and test running. The consultant will give the necessary instructions of the training program implemented by the equipment supplier.

2-2-4-7 Soft Component (Technical Assistance) Plan

This Project will be implemented to procure mammography and its related equipment for the 39 health facilities planned for equipment installation and it is expected to drastically improve the breast cancer screening services of those facilities. To maintain the high operability of the procured equipment in an appropriate manner, however, it is necessary to reinforce the quality control of the equipment. For this purpose, soft components are recommended in consideration of the following points:

(1) Background to planning soft components

The Project for Breast Cancer Screening and Prevention Capacity Improvement is intended to install equipment for use in breast cancer screening services in 39 medical facilities throughout Serbia.

When operating the mammography unit, it is necessary to obtain high-resolution, high-contrast images of high quality with a low dose. To attain this effect, it is essential to use the radiography equipment at the performance required for mammography unit (hereinafter called “the Equipment”), to optimize the technical factors including the radiographic conditions, receiving system, developing process and removal of scattered radiation, and skill factors such as positioning and compressing the breasts, and to draw up and implement a total quality assurance program for these factors.

The member of the Working Group for the National Program for Prevention of Breast Cancer, as also recognized that mammography in Serbia, especially in local medical centers, has not yet reached the appropriate level in radiographic positioning and quality of mammograms. Therefore, reinforcement of the technical ability of radiologists and radiographers are called for. It is very important and significant to improve the technology in quality control of

mammographic images and equipment quality / accuracy control in Serbia in order to build the foundations of the Breast Cancer Screening System in Serbia. It is also important to support the establishment of the Breast Cancer Screening System and continuous use of the medical equipment to be procured in the Grant Aid Project with appropriate quality / accuracy, by making use of the soft components provided by Japanese engineers.

(2) Goal of soft components

The soft component is aimed at technical improvement in image control of the radiographs and in quality / accuracy control of the mammography unit in order to realize appropriate and effective use of the procured medical equipment. In particular, manuals for the daily maintenance procedures for the mammography unit and X-ray film processor that the radiographers will operate daily will be prepared in order to maintain the appropriate image quality of the radiographs, and training using the manuals will be furnished to improve the skills of the radiographers. These activities will be the first step toward standardizing the screening work by mammography and quality control work in Serbia in future.

(3) Outputs of soft components

The soft component will be introduced as a quality control tool for the radiographs and quality / accuracy control tool for the digital and analog mammography units and X-ray film processors by preparing the manuals for such equipment. A maintenance system and structure (including personnel) will be established by appointing a radiographer as the person responsible for quality / accuracy control and the equipment users, and quality / accuracy control will be reinforced at the same time.

(4) Responsibilities of implementing agency of Serbia

The MoH which is the implementing agency in Serbia will be responsible for arranging to invite members to participate in the workshops and training to be held at some of the health facilities, and for schedule adjustment, and also for the costs and expenses that may accrue from such workshops and on-the-job training.

2-2-4-8 Implementation Schedule

(1) Tender and tender-related works

The tender and tender-related works include final confirmation of the technical specifications of the equipment and preparation of the instruction to tenderers. This set of documents needs to be approved by the Serbian side. Then, the consultant will announce applicants, hold the tender, evaluate the submitted documents from applicants, nominate the

winner and help to conclude the supply contract between the MoH of Serbia and the supplier. This stage takes approximately four (4) months.

(2) Procurement and installation of equipment

After JICA verifies the supply contract between the MoH of Serbia and the equipment supplier, the supplier starts procuring the equipment in compliance with the contract documents. The works related to the equipment procurement, transportation and installation in the Project sites take about eight (8) months.

Based in the above, the work process after the signing of the E/N and G/A is outlined in Figure 2.1. The Soft Component Program is planned to be carried out three (3) months later after installation of the equipment. All components of the Project take about fifteen (15) months after the signing of the E/N and G/A.

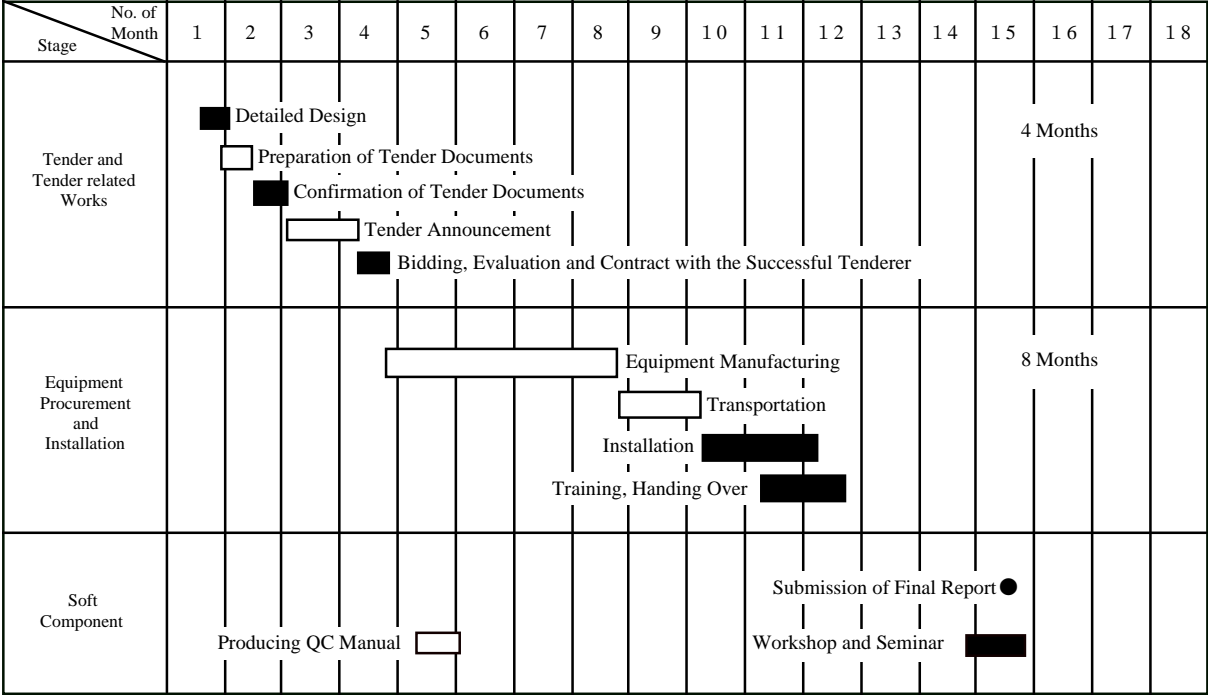


Fig. 2.1 Planned Project Implementation Schedule

2-3 Obligations of the Recipient Country

The general responsibilities of the Serbian side relating to the implementation of the requested Japanese Assistance are as follows;

- To provide the necessary data and information/documents for the Project,
- To provide primary works (radiation shielding, installation of power supply breakers, etc.) necessary for the installation of the equipment to be procured,
- To exempt any taxes of the medical equipment to be procured,
- To provide support for the supplier, such as prompt customs clearance of the equipment under the Project at ports of disembarkation in and outside Serbia,
- To exempt Japanese nationals who are staying in Serbia for providing services in connection to the implementation of the Project, from customs duties, internal taxes and fiscal levies which may be imposed in Serbia,
- To accord necessary promotion and security measures to Japanese nationals entering or staying in Serbia for the purpose of providing services and to their equipment brought in for the implementation of the Project,
- To conduct the Banking Arrangement (B/A), and to pay commissions (Advising commissions of A/Ps and payment commissions) associated with the issuance of the Authorization to Pay (A/P),
- To allocate the personnel / budget required for the effective implementation of the Project (including operation and maintenance costs of equipment procured using grant aid), and
- To bear all other expenses except covered by Japan, associated with the implementation of the Project.

2-4 Project Operation Plan

The maintenance of medical equipment at almost all Project sites is subcontracted (to an external medical equipment agent, etc.) and very few facilities employ a technical expert who is exclusively in charge of the repair of broken or malfunctioning equipment. In other words, the maintenance and management of medical equipment is basically either consigned as necessary to the private sector (in urban areas, agents of the medical equipment manufacturers), or, in most cases, a maintenance service contract is exchanged with such a firm. The maintenance service contracts are categorized into the following 3 types;

- Regular check only
- Regular check and replacement of some parts when necessary
- Regular check and replacement of all parts when necessary

The large-scale health facilities try to minimize maintenance costs by as far as possible having purchasing all their advanced and costly equipment, such as CT Scanner and/or MRI, from the same manufacturer and also by contracting out the maintenance of all the equipment to a single agent. However, some health facilities have budgetary difficulties in arranging the purchase of expensive spare parts such as X-ray tubes. With regard to the purchase of costly parts, some facilities have the custom of setting aside an appropriate proportion of their user fees; the MoH itself advises each health facility to set aside around 3% of their income from user fees for the maintenance and management of their facilities and equipment.

Thus, in most cases there is sufficient and timely preparation for maintenance and management costs for medical equipment, even when unexpected expenditures are necessary, with the exception of the purchase of costly parts such as X-ray tubes. With regard to breast cancer screening, it seems that the maintenance of the related medical equipment could be managed with financial backup, with a system of user fees refund being introduced for breast cancer screening at each health facility.

Although the inventory of medical equipment is controlled by the Institute of Public Health of Serbia, it is hard to say that the devices are kept appropriately up to date. In addition, no information is available as to whether the equipment is financed out of the government budget or out of donor agency funds. The Institute of Public Health of Serbia has a local office in each district and those district offices are obliged to submit twice a year to the main office a report on their activities including medical services.

2-5 Project Cost Estimation

2-5-1 Initial Cost Estimation

The total cost for the implementation of the project is estimated at approximately Yen (equivalent to approx RSD454 million). The breakdown of the costs to be borne by Serbia and Japan respectively is calculated as follows, based on the conditions mentioned in (3); however, those figures do not represent the maximum amount of grant aid funds in the Exchange of Notes (E/N) and Grant Agreement (G/A).

(1) Costs to be borne by Japan

The costs borne by the Japanese side is shown in the table 2.5. But the cost information to be covered by the Japanese side is not possible to open it to the public at the moment.

Table 2.5 Estimated Cost of the Japanese Assistance

(2) Costs to be borne by Serbia

The cost borne by the Serbian side is shown as follows:

Table 2.6 Estimated Costs to be borne by the Serbian Side

No	Items	Thousand RSD	Thousand J. Yen
1	Operation (running) and maintenance costs	115,904	166,241
2	Facilities renovation (see main report)	6,286	9,017
3	Payment commissions	488	700
4	A/P advising commissions	9	12
Total Costs		122,687	175,970

(3) Conditions of the Estimate

Date of estimate : April 2009

Currency exchange rate : US\$1.00 = 95.03 Japanese yen
: Euro1.00 = 135.24 Japanese yen
: RSD1.00 = 1.4343 Japanese yen
: Euro1.00 = 94.29 Serbia Dinar

Duration of Project Implementation Period

: Fifteen (15) months (including soft component activities)

Other

: This project will be implemented in line with the Japanese Grant Aid System

2-5-2 Operation and Maintenance Cost

(1) Estimated operation cost and its application

Table 2.7 shows the estimated cost of reagents and consumable supplies, which are indispensable for the operation of the equipment to be procured. This should be included in the initial project cost, on the assumption that the renewal of such items is essential. The quantity of each item has been calculated on the assumption that one set of mammography unit shall be used for 20 examinees per day (4 pictures per person) and shall be used for 4,800 examinees per year in the Serbian medical check-up program. It is also assumed that the mammography and other equipment will be renewed every 8 to 10 years.

The Serbian health administration operates what is called a medical / clinical treatment fee system; the medical treatment fee is paid from the medical insurance fund to each health facility to cover the cost of the breast cancer screening carried out. The refunded treatment fees are allocated to the operation of the facilities. The cost of contracting out the maintenance of the medical equipment to the external agents of the medical equipment manufacturers is also covered from the refunded treatment fee at each targeted health facility. As the treatment fee system is to be applied with regard to the breast cancer screening activities too, no substantial difficulties are anticipated in the allocation of funds to cover the cost of maintenance and management.

Table 2.7 Running Costs of the Planned Equipment (unit: RSD)

No.	Equipment	Q'ty	Consumables	Q'ty	U. Price	Total
1	Digital mammography	2	Printing film	38,400 Sheets	160	6,144,000
2	Analog mammography with CR system	23	Printing film	441,600 Sheets	160	70,656,000
3	Analog mammography	14	X-ray film	268,800 Films	120	32,256,000
4	Dry imager	25	Tonner	50 Pcs	100,000	5,000,000
5	X-ray film processor	14	Processing Solution	28	41,000	1,148,000
			Fixing Solution	28	15,000	700,000
				Boxes		
Total						115,904,000 (166 Mil. J.Y.)

Remarks: Amount to be consumed is calculated assuming the following conditions;

- Digital mammography : 4 sheets / person x 4,800 persons x 02 units
- Analog mammography + CR system : 4 sheets / person x 4,800 persons x 23 units
- Analog mammography : 4 sheets / person x 4,800 persons x 12 units

(2) Costs to be borne by Serbia for the installation of mammography

The related cost for the installation of the mammography units is estimated at RSD 6,287 thousand as summarized below. The renovation works that must be completed before the installation of the procured equipment should be carried out by each Project site under the guidance of the MoH. The maximum cost of the works per facility is estimated at Euro 7 thousand (no more than Japanese Yen one million) and the targeted facility should be able to cover this amount.

Table 2.8 Summarized estimate of cost of Renovation Works related to the Equipment Installation to be borne by Serbia (unit: RSD)

NO	Site No.	District	Health Facility	Costs
1	HC-01	Severnobacki	General Hospital Subotica	127,000
2	HC-02	Severnobanatski	Health Center Senta	112,000
3	HC-04	Kolubarski	Health Center Valjevo	0.00
4	HC-06	Branicevski	Health Center Petrovac	0.00
5	HC-08	Borski	Health Center Negotin	64,000
6	HC-09	Pomoravski	General Hospital Cuprija	32,000
7	HC-10	Borski	Health Center Kladovo	38,000
8	HC-11	Zajecarski	Health Center Knjazevac	279,000
9	HC-12	Zajecarski	Health Center Zajecar	270,000
10	HC-13	Zlatiborski	Health Center Uzice	613,000
11	HC-15	Moravicki	General Hospital Gornji Milanovac	0.00
12	HC-16	Raski	Health Center Kraljevo	293,000
13	HC-17	Rasinski	Health Center Krusevac	519,000
14	HC-18	Nisavski	Health Center Aleksinac	328,000
15	HC-19	Pirotski	Health Center Pirot	134,000
16	HC-20	Jablanicki	General Hospital Leskovac	47,000
17	HC-22	Sremski	General Hospital Sremska Mitrovica	96,000
18	PHC-02	Srednjobanatski	Dom Zdravlja Novi Becej	0.00
19	PHC-04	Juznobacki	Dom Zdravlja Novi Sad	223,000
20	PHC-06	Macvanski	Dom Zdravlja Bogatic	0.00
21	PHC-07	Sumadijski	Dom Zdravlja Kragujevac	60,000
22	PHC-08	Rasinski	Dom Zdravlja Trstenik	0.00
23	PHC-09	Nisavski	Dom Zdravlja Nis	48,000
24	PHC-10	Pcinjski	Dom Zdravlja Bujanovac	453,000
25	PHC-11	Beograd	Dom Zdravlja Grocka	173,000
26	PHC-12	Beograd	Dom Zdravlja Zemun	377,000
27	PHC-13	Beograd	Dom Zdravlja Lazarevac	0.00
28	PHC-14	Beograd	Dom Zdravlja Novi Beograd	17,000
29	PHC-15	Beograd	Dom Zdravlja Obrenovac	613,000
30	PHC-16	Beograd	Dom Zdravlja Palilula	660,000
31	PHC-17	Beograd	Dom Zdravlja Rakovica	236,000
32	PHC-18	Beograd	Dom Zdravlja Stari Grad	471,000
Total				6,287,000

2-6 Other Relevant Issues

(1) Training and allocation of medical personnel

In order for the targeted facilities to function as currently, it is necessary to secure at least the current levels of medical personnel and also to ensure quality/accuracy control by training personnel in mammography. In order to secure personnel staffing levels, it is necessary to take regular measures to increase the number of personnel, in the same manner as before.

(2) Securing funds for operating and maintaining medical equipment and for operating breast cancer-screening services

At present, the MoH appropriates special grants for the National Program for Prevention of Breast Cancer. However, when the breast cancer screening becomes routine, the screening will be funded not by the government grants but by a refund from the Health Insurance Fund. It is necessary for each medical facility to make continuous arrangements for funding to operate the equipment and cancer screening services.

Chapter 3 Project Evaluation and Recommendations

CHAPTER 3 PROJECT EVALUATION AND RECOMMENDATIONS

3-1 Project Effect

The following effects can be expected as a result of implementing the Project. The direct effects shown here will need to be reviewed after a period of about 2 cycles (4 years) of the breast cancer screening activities.

Table 3.1 Effects of the Project

Current status and issues	Measures taken in the Project	Direct effects/Degree of improvement	Indirect effects/Degree of improvement
The existing mammography equipment is outdated. In addition, this is the first attempt by Serbia to introduce a breast cancer screening system: there is not enough equipment, and so not enough screening services have been provided in terms of quantity.	Procurement of the following equipment: <ul style="list-style-type: none"> • Mammography units • CR systems • Dry imagers • X-ray film processors • X-ray film viewers 	<ul style="list-style-type: none"> • The number of those who examine it increases to 195,000 people for two years. • The number of discoveries of breast cancer patients (new enrollment) increases for two years. • The number of discoveries of early stage breast cancer (up to stage 1) increases for two years. 	<ul style="list-style-type: none"> • The earlier detection rate of the breast cancer increases by the screening system of the breast cancer being improved. • Understanding and consideration of the people's breast cancer screenings will improve by strengthening the screening system and being executed the screenings. And, the number of breast cancer screening in whole Serbian country increases.
It cannot be said that there has been proper accuracy and/or quality control for mammography unit and mammography related medical equipment of breast X-ray photography / diagnosis. It is difficult to secure good-quality images at facilities in any part of Serbia, therefore radiographers and relevant staff needs to improve their skill so that mammograms (breast x-ray photographs) of guaranteed quality can be taken at any facility.	A soft component will be provided for the purpose of enhancing knowledge of/skill in accuracy control for mammography equipment and X-ray film processors, especially for radiological technologists (to ensure good-quality mammograms).	Radiographers at targeted medical facilities will be able to implement a proper accuracy control plan for mammography unit and X-ray film processors, so that mammograms of consistent good quality can be taken.	<ul style="list-style-type: none"> • The death due to breast cancer decreases by earlier detection and the early treatment of the breast cancer being conducted.

3-2 Recommendations

It is judged that Serbia needs to tackle the following issues for the continuous and effective use and maintenance/management of the medical equipment to be procured by the Project.

(1) Budgetary provision deemed necessary for the operation of check-up activities

This is the first attempt in Serbia to introduce a breast cancer screening system, and at present the Health Insurance Fund has not established the medical fees to be refunded for screening activities. However, in the pilot schemes currently in operation using mobile clinics, radiologists and radiological technologists are paid RSD300 and RSD150 respectively for each individual screening. Unfortunately, these fees do not seem to be a kind of revolving funding used for related consumables, such as film. However, if it is possible for such fees to be appropriated for screening operating expenses, including the purchase of consumables, more than 50% of the screening operating expenses, if not the whole amount, can be recovered.

The MoH has appropriated approx. RSD 200 million (about 280 million yen) as the FY2010 budget for major cancer measures. 60-70% of the budget is appropriated for activities related to breast cancer screening, so that the current pilot schemes using mobile clinics have operated smoothly. However, in order for the screening services to be covered by medical insurance, it is necessary to consider not only remuneration to medical staff but also the revolving funds used for requisite consumables, such as film. The MoH and those concerned with the Health Insurance Fund need to deal promptly with the question of how to operating expenses are to be covered in the long term, including the securing of financial resources and the establishment of screening fees to be covered, focusing on the adoption of various cancer screening systems.

(2) Introduction and use of related information for breast cancer screening

It is necessary that measures be taken not only for the maintenance of the medical equipment for breast cancer screening but also for the establishment of appropriate indicators and the collection and use of important statistical data for the evaluation of the activities and outcomes of the breast cancer screening program. For example, it is important to gather and maintain appropriate data including not only the number (percentage) of people who have had the screening but also the number (percentage) of people who require further examination, the number (percentage) of people who have had a further examination, the number (percentage) of cases in which cancer has been detected and the number (percentage) of cases in which early-stage cancer has been detected. Regular monitoring and evaluation of these indicators following completion of the implementation of this Project will be essential for improving the efficiency of facility operation and the quality of the breast cancer screening services. It is expected that the establishment of such an operating system will lead to a reduction in the

number of deaths due to breast cancer, which is the overall goal of this Project.

(3) Development of the capacity of the radiologists and radiographers working at the target health facilities

The committee members of the working group for the National Program for Prevention of Breast Cancer of Serbia prepared a plan for training in mammography for the medical personnel (radiologists and radiographers) working at the health facilities at which this Project is to be implemented, and selected the training institutions and training periods. In the prepared training plan, training of the personnel concerned will be completed at all the facilities concerned by the first quarter of 2011, previous to the installation of the equipment to be provided in this Project. It is important that the medical personnel be provided with sufficient training without delay, as this will contribute to a qualitative and quantitative improvement in the screening services.

(4) Accuracy and quality control of the mammograms for breast cancer screening

It is considered that the establishment in Serbia of an organization corresponding to the Japanese Central Committee on Quality Control of Mammographic Screening together with the high-level standardization of mammography accuracy and quality throughout the country will form the basis of the appropriate operation of the breast cancer screening program, which will lead to a reduction in the number of deaths from breast cancer. The MoH of Serbia fully recognized the importance of accuracy control in mammography and intends to establish an accuracy control committee composed of the members of the National Program for Prevention of Breast Cancer and relevant personnel from the VINCA Institute of Nuclear Sciences; this committee would be responsible for radiological accuracy control in Serbia. The establishment of a committee for accuracy control in mammography will be extremely important in the operation of the screening services, as the operation of such a committee will contribute significantly to ensuring that mammography is of equal quality at medical facilities in both rural areas and the capital, and to the diagnosis of breast cancer at the rural medical facilities.

This Project plans to provide technical assistance through Soft component by a Japanese consultant as part of this Project for the acquisition and establishment of the techniques for appropriate accuracy and quality control of the procured equipment and mammograms.

Appendices

1. Member List of the Study Team
2. Study Schedule
3. List of Parties Concerned in the Recipient Country
4. Minutes of Discussions
5. Soft Component (Technical Assistance) Plan

Appendices

1. Member List of the Study Team

(1) Preparatory Survey (2)

No	Name	Job Title	Occupation
1	Mr. Satoru KUROSAWA	Leader	Chief Representative, Japan International Cooperation Agency, Balkan Office
2	Dr. Shunro MATSUMOTO	Technical Advisor (Radiology HRD)	Associate Professor, Department of Radiology, Oita University Faculty of Medicine and Oita University Hospital
3	Mr. Yasunori MURAKAMI	Technical Advisor (Examination Techniques)	Head of Medical Technology Department/ Chief Radiological Technologist, Medical Technology Department (Radiological Center), Oita University Hospital
4	Ms. Megumi MASUI	Cooperation Planning	Program Officer, Health Systems Division, Human Development Department, JICA HQs
5	Mr. Tamotsu NOZAKI	Chief Consultant/ Equipment Plan 1	Fujita Planning Co., Ltd.
6	Mr. Masayuki AOKI	Equipment Plan 2/ Facility Planning	Fujita Planning Co., Ltd.
7	Ms. Michiko FUJIMOTO	Procurement Plan	Fujita Planning Co., Ltd.

(2) Explanation of Draft Outline Design

No	Name	Job Title	Occupation
1	Mr. Satoru KUROSAWA	Leader	Chief Representative, Japan International Cooperation Agency, Balkan Office
2	Ms. Megumi MASUI	Cooperation Planning	Program Officer, Health Systems Division, Human Development Department, JICA HQs
3	Mr. Tamotsu NOZAKI	Chief Consultant/ Equipment Plan 1	Fujita Planning Co., Ltd.
4	Mr. Masayuki AOKI	Equipment Plan 2/ Facility Planning	Fujita Planning Co., Ltd.

2. Study Schedule

(1) Preparatory Survey (2)

Members		JICA Members concerned			Consultant Members			
		Leader	TA (HRD)	TA (RT)	Co Planning	Chief /Equip 1	Equip. 2/ Facility	Procurement
1	27 Oct 09 (T)					Lv. Narita, Av. GB		
2	28 Oct 09 (W)					JICA Balkan, MOH, and WG		
3	29 Oct 09 (T)					EU and WB	HC-02, PHC-03	
4	30 Oct 09 (F)					CC-04, PHC-02	PHC-07, HC-16	
5	31 Oct 09 (S)					Documentation		
6	1 Nov 09 (S)					Documentation		
7	2 Nov 09 (M)					PHC-15, PHC-06	HC-09, HC-18	
8	3 Nov 09 (T)					HC-05, HC-06	PHC-09, HC-20	
9	4 Nov 09 (W)					PHC-18, PHC-16	CC-01, HC-19	
10	5 Nov 09 (T)					HC-17, PHC-08	HC-11, HC-12	
11	6 Nov 09 (F)					PHC-10	HC-08, HC-10	
12	7 Nov 09 (S)					Documentation		
13	8 Nov 09 (S)					Documentation		
14	9 Nov 09 (M)					HC-15, HC-13	HC-22, PHC-04	
15	10 Nov 09 (T)		Lv. Oita, Av. Narita			PHC-13, HC-04	HC-01, HC-03	
16	11 Nov 09 (W)		Lv. Narita, via Munich, Av. BG			CC-03, CC-02	PHC-11, PHC-17	
17	12 Nov 09 (T)		JIAC Balkan, MOH and WG				PHC-14, PHC-12	
18	13 Nov (F)		Site Survey, QA Seminar, etc					Lv. Narita, Av. BG
19	14 Nov 09 (S)		Documentation					
20	15 Nov 09 (S)		Documentation					
21	16 Nov 09 (M)		Discussion on Minutes of Discussions (M/D)					Equipment Agents
22	17 Nov 09 (T)		Discussion on Minutes of Discussions (M/D)					Equipment Agents
23	18 Nov 09 (W)		Signing the M/D, Report to EOJ					Equipment Agents
24	19 Nov 09 (T)		Lv. BG → Av. Munich →			Survey		Equipment Agents
25	20 Nov 09 (F)		Lv. Narita to Oita	Av. Narita		Survey		Equipment Agents
26	21 Nov 09 (S)					Documentation		
27	22 Nov 09 (S)					Documentation		
28	23 Nov 09 (M)					Survey		Transportation Agents
29	24 Nov 09 (T)					JICA Balkan, MOH, and WG		Transportation Agents
30	25 Nov 09 (W)					Lv. BG, via Munich,		
31	26 Nov 09 (T)					Av. Narita		

Visit Schedule of the Project Sites

Date	Time	Member	Site No.	District	Institutions
29-October	8:30	II	HC-02	Severnobanatski	Health Centre Senta
29-October	12:30	II	PHC-03	Severnobacki	Medical Centre (Dom zdravlja) Mali Idjos
30-October	8:15	I	CC-04	Belgrade	Clinic-hospital Centre "Zemun"
30-October	11:45	I	PHC-02	Srednjobanatski	Medical Centre (Dom zdravlja) Novi Becej
30-October	8:30	II	PHC-07	Sumadijski	Medical Centre (Dom zdravlja) Kragujevac
30-October	12:30	II	HC-16	Raski	Health Centre Kraljevo
2-November	9:00	I	PHC-15	Belgrade	Medical Centre (Dom zdravlja) Obrenovac
2-November	13:00	I	PHC-06	Macvanski	Medical Centre (Dom zdravlja) Bogatic
2-November	8:30	II	HC-09	Pomoravski	General Hospital Cuprija
2-November	12:30	II	HC-18	Nisavski	Health Centre Aleksinac
3-November	9:00	I	HC-05	Podunavski	Health Centre Smederevo
3-November	12:00	I	HC-06	Branicevski	Health Centre Petrovac
3-November	8:15	II	PHC-09	Nisavski	Medical Centre (Dom zdravlja) Nis
3-November	12:00	II	HC-20	Jablanicki	General Hospital Leskovac
4-November	8:15	I	PHC-18	Belgrade	Medical Centre (Dom zdravlja) Stari Grad
4-November	11:45	I	PHC-16	Belgrade	Medical Centre (Dom zdravlja) Palilula
4-November	8:15	II	CC-01	Nisavski	Clinical Centre Nis
4-November	11:30	II	HC-19	Pirotski	Health Centre Pirot
5-November	9:00	I	HC-17	Rasinski	Health Centre Krusevac
5-November	12:30	I	PHC-08	Rasinski	Medical Centre (Dom zdravlja) Trstenik
5-November	8:30	II	HC-11	Zajecarski	Health Centre Knjazevac
5-November	12:30	II	HC-12	Zajecarski	Health Centre Zajecar
6-November	9:30	I	PHC-10	Pcinjski	Medical Centre (Dom zdravlja) Bujanovac
6-November	8:15	II	HC-08	Borski	Health Centre Negotin
6-November	12:00	II	HC-10	Borski	Health Centre Kladovo
9-November	9:00	I	HC-15	Moravicki	General Hospital Gornji Milanovac
9-November	13:00	I	HC-13	Zlatiborski	Health Centre Uzice
9-November	8:00	II	HC-22	Sremski	General Hospital Sremska Mitrovica
9-November	12:00	II	PHC-04	Juznobacki	Medical Centre (Dom zdravlja) Novi Sad
10-November	9:00	I	PHC-13	Belgrade	Medical Centre (Dom zdravlja) Lazarevac
10-November	13:30	I	HC-04	Kolubarski	Health Centre Valjevo
10-November	8:30	II	HC-01	Severnobacki	General hospital Subotica
10-November	12:30	II	HC-03	Zapadnobacki	General Hospital Sombor
11-November	8:15	I	CC-03	Belgrade	Clinic-hospital Centre "Zvezdara"
11-November	10:45	I	CC-02	Belgrade	Clinic-hospital Centre "Dr. Dragisa M - D"
11-November	8:00	II	PHC-11	Belgrade	Medical Centre (Dom zdravlja) Grocka
11-November	11:30	II	PHC-17	Belgrade	Medical Centre (Dom zdravlja) Rakovica
12-November	8:00	II	PHC-14	Belgrade	Medical Centre (Dom zdravlja) Novi Beograd
12-November	11:30	II	PHC-12	Belgrade	Medical Centre (Dom zdravlja) Zemun

(2) Explanation of Draft Outline Design

Date		JICA Members		Consultant Members	
		Leader	Cooperation Planning	Chief Consultant / EP 1	EP II / Facility Planning
		Satoru KUROSAWA	Megumi MASUI	Tamotsu NOZAKI	Masayuki AOKI
1	07 Mar 10 (S)		Lv. Narita 13:20 (LH715) → Av. Munich 17:45 Lv. Munich 19:25 (LH3404) → Av. BG 20:50		
2	08 Mar 10 (M)	Meeting with authorities concerned (JICA Balkan Office, Ministry Health, Breast Cancer Screening Working Group members)			
3	09 Mar 10 (T)	Explanation of Draft Report to MOH and Breast Cancer Screening WG Members, Discussion with MOH, EU and the Team			
4	10 Mar 10 (W)	Discussion with MOH and WG members (Minutes of Discussions, and Technical Specifications, etc)			
5	11 Mar 10 (T)	Discussion with MOH and WG members (Minutes of Discussions, and Technical Specifications, etc)			
6	12 Mar 10 (F)	Signing the Minutes of Discussions, Report to Embassy of Japan in Serbia			
7	13 Mar 10 (S)		Lv. BG 12:50 (LH3401) → Av. Munich 14:30, Lv. Munich 15:40 (LH714) →		
8	14 Mar 10 (S)		Av. Narita 11:25		

3. List of Parties Concerned in the Recipient Country

(1) Ministry of Health

- MSc Tomislav Stantic State Secretary
- Dr. Ka Natalija Petrovic Sector for International Cooperation and EU Integration
- Dr. Danijela Urosevic Sector for International Cooperation and EU Integration
- Ms. Srencevic Nada Sector for European Union Integration,
International Collaboration and Project, Coordinator
- Ms. Jelena Pavrovic Sector for European Union Integration,
International Collaboration and Project, Coordinator

(2) Institute of Radiology and Oncology, Serbia (Beograd)

- Prof. Dr. Zoran Rakocevic Head of Nuclear Medicine, Head of Screening Committee
- Dr. Biljana Janovljevic Radiologist
- Dr. Ka Tatijana Pavlovich Radiologist
- Ms. Jeljka Ljepoja Senior Radiographer, Mammography

(3) Institute of Radiology and Oncology, Vojvodina (Novi Sad)

- Dr. Dragana Dilos Ivanovic Radiologist, Diagnostic Section
- Dr. Mladen Prvulovic Radiologist, Radiotherapy Department

(4) Institute of Nuclear Sciences, VINCA

- Mr. Milojko Kivasevic Director of Laboratory
- Dr. Olovera Ciraj-Bjelac Medical Physicist, Assistant Professor

(5) Bezanijska Kosa Clinical Hospital Center (Beograd)

- Dr. Vladimir Kovcin Director
- Dr. Jovica Saponiski Chief, Radiology Department
- Dr. Magdacena Stefanovic Radiologist
- Ms. Sreiljana ZIvotic Radiographer

(6) Project Sites

- Zemun CHC Dr. Dragos Stojanovic Director
- Novi Becej DZ Dr. Anelka Korovliev Director, Dentist
- Obrenovac DZ Dr. Ka Maja Todorovic Director
- Bogatic DZ Dr. Ka Vesna Stanojcic Director

- Smederevo HC	Dr. Nenad Djordjevic	Director
- Petrovac HC	Dr. Anelka Boskovic-Nesic	Acting Director
- Stari Grad DZ	Dr. Ljubisa Perisic	Director
- Palilula DZ	Dr. Ka Jadranka Dvrakovic	Acting Director
- Krusevac HC	Dr. Vojkan Kulic	Director
- Trstenik DZ	Dr. Radovan Popovic	Director
- Bujanovac DZ	Dr. Bajram Hasani	Director
- Gornji Milanovac HC	Dr. Miro Razarevic	Director
- Uzice HC	Dr. Zoran Lazovic	Director
- Lazarevac DZ	Dr. Miodrag Durkovic	Director
- Valjevo HC	Dr. Ilija Tripkovic	Director
- Zvezdara CHC	Dr. Svetozar Pervulov	Radiologist
- Dr. Dragisa M-D CHC	Dr. Djordje Larosevic	Radiologist
- Senta HC	Dr. Jene Tari	Director
- Mali Idjos DZ	Dr. Deak Tibor	Director
- Kragujevac DZ	Dr. Radomila Obradovic	Director
- Kraljevo HC	Dr. Milka Velickovic	Chief of Radiology
- Cuprija HC	Dr. Predrag Drenovakovic	Director
- Aleksinac HC	Dr. Goran Dzeledinovic	Director
- Nis DZ	Dr. Milan Manojlovic	Director
- Leskovac HC	Dr. Zoran Ceranic	Director
- CC Nis (Oncology)	Dr. Sasa Ljubenkovic	Chief of Radiotherapy
- CC Nis (Radiology)	Dr. Patar Bosnjakovic	Director
- Pirot HC	Dr. Radovan Ilic	Director
- Krusevac HC	Dr. Mikica Vidojevic	Director
- Zajecar HC	Dr. Mirko Veljkovic	Director
- Negotin HC	Prim, Dr. Miomir Petkovic	Director
- Kladovo HC	Dr. Dragan Arandelovic	Director
- Sremska Mitrovica HC	Dr. Goran Ivic	Director
- Novi Sad PHC	Dr. Jasmina Peuric	Finance Director
- Subotica HC	Dr. Goran Bicanin	Director
- Sombor HC	Dr. Milan Grba	Assistant Director
- Grocka DZ	Dr. Dragisa Stenojevic	Director
- Rakovica DZ	Dr. Zorica Jovanovi	Director
- Novi Beograd DZ	Dr. Dragana Gojsino	Assistant Director
- Zemun DZ	Dr. Branka Cemerikic	Director

(7) Medical Equipment Manufacturers Agent in Serbia

- Agfa Health Care, Hungary Llc.

Mr. Gyorgy Hodosi Regional Maneger, Eastern Europe

- Agfa Health Care, Serbia Representative Office

Mr. Marko Pandrc Sales and Maketing Manager

- Alpha Imaging

Mr. Predrag Bjeletic General Director

Mr. Zoran Pavkovic Sales Manager

Mr. Zoran Jekic Sales Engineer

- Beolaser

Mr. Dragan Rokic Director

Mr. Branko Martinovic Marketing Manager

- GE Holdings

Mr. Yugo Cvetkovic Area Manager Macedonia, Montenegro, Serbia

- Medicom

Mr. Milan Jovanic Deputy Director

- Senzal Trade

Mr. Sava Nikolic Director

- Siemens, Beograd

Mr. Ratko Krakovic Healthcare Country Lead

- Timco

Dipl.ing. Momcilo Miric Director

(8) Transportation Company

- Adamsped Subotica Mr. Aleksandar Cvetanović Commercial Manager

- Californiasped Mr. Karalic Ljubisa General Manager

- Milsped Mr. Dejan Petrovic Custom Department Director

- Transped Proteam Mr. Nikola Kostur Logistic Manager

(9) Embassy of Japan in Serbia

- Mr. Toshio Tsunozaki Ambassador

- Mr. Teruhiko Shinada Deputy Head of Mission, Counsellor

- Mr. Hiroyuki Yamashita Second Secretary

(10) JICA Balkan Office

- | | |
|-----------------------|--------------------------------|
| - Mr. Satoru Kurosawa | Resident Representative |
| - Mr. Ken Yamada | Deputy Resident Representative |
| - Mr. Yohei Takahashi | Representative |

4. Minutes of Discussions

(1) Preparatory Survey (2)

MINUTES OF DISCUSSIONS
PREPARATORY SURVEY (2) ON THE PROJECT FOR
BREAST CANCER SCREENING AND PREVENTION CAPACITY IMPROVEMENT
IN THE REPUBLIC OF SERBIA

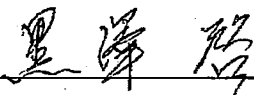
Based on the results of the Preparatory Survey 1, the Government of Japan decided to conduct a Preparatory Survey 2 on the Project for Breast Cancer Screening and Prevention Capacity Improvement in the Republic of Serbia (hereinafter referred to as "the Project") and entrusted the study to the Japan International Cooperation Agency (hereinafter referred to as "JICA").

JICA sent to the Republic of Serbia (hereinafter referred to as "Serbia") the Preparatory Survey 2 Team (hereinafter referred to as "the Team"), which is headed by Mr. Satoru Kurosawa, Chief Representative, JICA Balkan Office, and is scheduled to stay in the country from October 27 to November 25.

The Team held discussions with the officials concerned of the Government of Serbia and conducted a field survey at the study area.

In the course of discussions and field survey, both parties confirmed the main items described on the attached sheets. The Team will proceed to further works and prepare the Preparatory Survey 2 Report.

Beograd, November 18, 2009



Mr. Satoru Kurosawa

Leader
Preparatory Survey 2 Team
Japan International Cooperation Agency
Japan



MSc Tomislav Stantic, MD

State Secretary
Ministry of Health
The Republic of Serbia



ATTACHMENT

1. Objective of the Project

The objective of the Project is to improve screening and early detection of breast cancer through provision of medical equipment.

2. Responsible and Implementing Institution

2-1. The Responsible Institution is the Ministry of Health, the Government of Serbia.

2-2. The Implementing Institution is the Ministry of Health, the Government of Serbia.

3. Project Sites and Items Requested by the Government of Serbia

After discussions with the Team, the project sites and items described in Annex-1 were finally requested by the Serbian side. JICA will assess the appropriateness of the request and will recommend to the Government of Japan for approval.

4. Japan's Grant Aid Scheme

The Serbian side understands the Japan's Grant Aid Scheme and the necessary measures to be taken by the Government of Serbia as explained by the Team and described in Annex-2 and Annex-3 of the Minutes of Discussions signed by both parties on November 18.

5. Schedule of the Survey

5-1. The consultants will proceed to further studies in Serbia until November 25.

5-2. JICA will prepare the draft report in English and dispatch a mission in order to explain its contents.

5-3. In case the contents of the report are accepted in principle by the Government of Serbia, JICA will complete the final report and send it to the Government of Serbia.

6. Other Relevant Issues

6-1. Trainings of Radiologists and Radiographers

The Serbian side will conduct necessary trainings of radiologists and radiographers before the installation of the medical equipment.

6-2. Operation and Maintenance of the Medical Equipment

The Serbian side will take necessary measures for appropriate operation and maintenance of the medical equipment.

6-3. Preparatory Work for the installation of the Medical Equipment

The Serbian side will renovate and/or improve the appropriate X-ray protection rooms to meet the Serbian regulation and remove the unnecessary existing equipment before

the installation of the medical equipment. The Serbian side will also prepare proper reading rooms.

6-4. Quality Control

The Serbian side will establish the central committee on quality control of mammographic screening, and the committee will take necessary measures to improve the quality control.

6-5. Budgets and Workforce to Implement the Screening

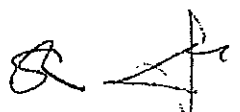
The Serbian side will secure and allocate the budgets and workforce enough to implement the breast cancer screening program, and set the item for breast cancer screening in the Health Fund.

6-6. Technical Assistance

The Serbian side requested to the Team the technical assistance regarding quality control under the Project.

6-7. Donor Coordination

The Serbian side confirmed the coordination among the donors to avoid the duplication of the medical equipment and to promote harmonization.



No.	Site No.	District	Health Institution	Mammography Digital / Analog with Accessories	Film Processor Film viewer and Phantom	Existing Digital Unit	Existing Mammography	Number of Target Group (High : >30000)	Radiologist (Mammography Experienced)	Radiographer (Mammography Experienced)	Priority for Digitalization	Type of Package
1	HC-04	Kolubarski district	Health Centre Valjevo	Digital	-	YES	YES	16,603	11(3)	32(4)	A	Digital
2	HC-16	Raski district	Health Centre Kraljevo	Digital	-	YES	YES	16,000	10(6)	21(23)	A	Digital
Highest priority for Digital Mammography												
Digital												
Digital Mammography, Work Station, Dry Imager												
Digital												

No.	Site No.	District	Health Institution	Mammography Digital / Analog with Accessories	Film Processor Film viewer and Phantom	Existing Digital Unit	Existing Mammography	Number of Target Group (High : >30000)	Radiologist (Mammography Experienced)	Radiographer (Mammography Experienced)	Priority for Digitalization	Type of Package
3	HC-01	Severnobacki district	General Hospital Subotica	Analog(B)	-	YES	YES	25,825	12(2)	24(3)	A	Analog(A)
4	HC-02	Severnobanatski district	Health Centre Senta	Analog(A)	-	NO	YES	29,130	5(2)	10(5)	B	Analog(A) or (B)
5	HC-06	Branicevski district	Health Centre Petrovac	Analog(A)	-	NO	NO	14,609	1(0)	3(0)	C	Analog(B)
6	HC-08	Borski district	Health Centre Negotin	Analog(A)	-	NO	NO	7,578	4(3)	8(2)	C	Analog(B)
7	HC-09	Pomoravski district	General Hospital Cuprija	Analog(A)	-	YES	YES	60,000	10(6)	18(10)	A	Analog(A)
8	HC-10	Borski district	Health Centre Kladovo	Analog(A)	-	NO	YES	23,614	3(1)	13(8)	B	Analog(A) or (B)
9	HC-11	Zajecarski district	Health Centre Knjazevac	Analog(A)	-	NO	NO	9,989	3(0)	6(0)	C	Analog(B)
10	HC-12	Zajecarski district	Health Centre Zajecar	Analog(A)	-	YES	YES	23,527	5(5)	13(7)	A	Analog(A)
11	HC-13	Zlatiborski district	Health Centre Užice	Analog(A)	-	YES	NO	13,810	7(0)	25(0)	A	Analog(A)
12	HC-15	Moravicki district	General Hospital Gornji Milanovac	Analog(A)	-	NO	NO	8,500	2(0)	5(0)	C	Analog(B)
13	HC-17	Rasinski district	Health Centre Knisevac	Analog(A)	-	YES	YES	22,672	5(2)	21(21)	A	Analog(A)
14	HC-18	Nišavski district	Health Centre Aleksinac	Analog(A)	-	NO	NO	10,000	3(0)	4(0)	C	Analog(B)
15	HC-19	Prizorski district	Health Centre Pirot	Analog(B)	-	YES	YES	14,350	8(4)	15(5)	A	Analog(A)
16	HC-20	Jablanicki district	General Hospital Leskovac	Analog(B)	-	YES	YES (License in DZ)	30,000	11(11)	16(14)	A	Analog(A)
17	HC-22	Sremski district	General Hospital Sremska Mitrovica	Analog(A)	-	YES	YES	55,250	10(9)	16(4)	A	Analog(A)
18	PHC-02	Šumadijski county	Dom Zdravlja Novi Bečej	Analog(A)	-	NO	NO	6,315	0(0)	2(0)	C	Analog(B)
19	PHC-04	Juznobački district	Dom Zdravlja Novi Sad	Analog(A)	-	NO	YES	56,922	10(4)	17(10)	B	Analog(A) or (B)
20	PHC-06	Maevanski district	Dom Zdravlja Bogatic	Analog(A)	-	NO	NO	4,000	0(0)	2(0)	C	Analog(B)

No.	Site No.	District	Health Institution	Mammography Digital / Analog with Accessories	Film Processor and Phantom	Existing Digital Unit	Existing Mammography	Number of Target Group (High: >30000)	Radiologist (Mammography Experienced)	Radiographer (Mammography Experienced)	Priority for Digitalization	Type of Package
21	PHC-07	Sumadijski district	Dom Zdravlja Kragujevac	Analog(A)	-	NO	NO	36,000	2(0)	4(0)	B	Analog(A) or (B)
22	PHC-08	Rasanski district	Dom Zdravlja Trstenik	Analog(A)	-	NO	NO	13,941	1(0)	3(0)	C	Analog(B)
23	PHC-09	Nisavski district	Dom Zdravlja Nis	Analog(A)	-	NO	NO	37,519	7(1)	15(0)	B	Analog(A) or (B)
24	PHC-10	Podjaski district	Dom Zdravlja Bajina Voca	Analog(A)	-	NO	NO	12,331	1(0)	3(0)	C	Analog(B)
25	PHC-11	City of Belgrade	Dom Zdravlja Grocka	Analog(A)	-	NO	NO	13,150	2(0)	4(0)	C	Analog(B)
26	PHC-12	City of Belgrade	Dom Zdravlja Zemun	Analog(A)	-	NO	NO	40,000	4(0)	8(0)	B	Analog(A) or (B)
27	PHC-13	City of Belgrade	Dom Zdravlja Lazarevac	Analog(A)	-	NO	YES	15,000	3(3)	5(5)	B	Analog(A) or (B)
28	PHC-14	City of Belgrade	Dom Zdravlja Novi Beograd	Analog(A)	-	YES	NO	34,156	9(0)	18(0)	A	Analog(A)
29	PHC-15	City of Belgrade	Dom Zdravlja Orenovao	Analog(A)	-	NO	NO	11,967	1(1)	5(0)	C	Analog(B)
30	PHC-16	City of Belgrade	Dom Zdravlja Palitula	Analog(A)	-	NO	NO	10,000	4(0)	7(0)	B	Analog(A) or (B)
31	PHC-17	City of Belgrade	Dom Zdravlja Rakovica	Analog(A)	-	NO	NO	15,000	2(0)	4(0)	C	Analog(B)
32	PHC-18	City of Belgrade	Dom Zdravlja Start Grad	Analog(A)	-	YES	NO	11,260	2(0)	5(0)	A	Analog(A)
			Digital Mammography with Accessories	2	-							
			Analog Mammography with Accessories	30	-							

Highest priority for Analog Mammography with CR

High priority for Analog Mammography with CR

Analog Mammography

Analog Mammography, CR System, Dry Imager, Film Viewer
Analog Mammography, Film Processor, Film ViewerA 10
B 8
C 12

No.	Site No.	District	Health Institution	Mammography Digital / Analog with Accessories	Film Processor and Phantom	Existing Digital Unit	Existing Mammography	Number of Target Group (High: >30000)	Radiologist (Mammography Experienced)	Radiographer (Mammography Experienced)	Priority for Digitalization	Type of Package
33	CC-01	Nisavski district	Clinical Centre Nis(Oncology)	-	1 set	NO	YES	0	11(3)	16(10)	C	Accessories(B)
34	CC-02	City of Belgrade	Clinic-hospital Centre "Dr. Dragisa Misovic - Dedinje"	-	1 set	YES	YES	5,796; 6,816; 8,376; 10,368; 12,360	13(5)	29(6)	A	Accessories(A)
35	CC-03	City of Belgrade	Clinic-hospital Centre "Zvezdara"	-	1 set	YES	YES	273; 3,616; 4,368; 5,120	13(6)	32(10)	A	Accessories(A)
36	CC-04	City of Belgrade	Clinic-hospital Centre "Zemun"	-	1 set	YES	YES	Zemun Novi Beograd Start Grad Vrnjačke Banje	12(2)	26(4)	A	Accessories(A)
37	HC-03	Zapadnobacki district	General Hospital Sombor	-	1 set	YES	YES	40,000	10(5)	16(3)	A	Accessories(A)
38	HC-05	Podunavski district	Health Centre Smederevo	-	1 set	YES	YES	19,000	6(6)	17(9)	A	Accessories(A)

No.	Site No.	District	Health Institution	Mammography Digital / Analog with Accessories	Film Processor Film Viewer and Phantom	Existing Digital Unit	Existing Mammography	Number of Target Group (High : >30000)	Radiologist (Mammo Experienced)	Radiographer (Mammo Experienced)	Priority for Digitalization	Type of Package
39	PHC-03	Severnozhsk district	Dom Zdravlja Mali Idjos	-	1 set	NO	YES	4,266	1(1)	2(2)	C	Accessories(B)

*Highest priority for CR reader and Imager with other accessories.
 *Film Processor with other accessories.

Accessories(A)	CR System, Dry Imager, Film Viewer
Accessories(B)	Film Processor, Film Viewer

A	5
C	2

JAPAN'S GRANT AID

The Government of Japan (hereinafter referred to as "the GOJ") is implementing the organizational reforms to improve the quality of ODA operations, and as a part of this realignment, a new JICA law was entered into effect on October 1, 2008. Based on this law and the decision of the GOJ, JICA has become the executing agency of the Grant Aid for General Projects, for Fisheries and for Cultural Cooperation, etc.

The Grant Aid is non-reimbursable fund provided to a recipient country to procure the facilities, equipment and services (engineering services and transportation of the products, etc.) for its economic and social development in accordance with the relevant laws and regulations of Japan. The Grant Aid is not supplied through the donation of materials as such.

1. Grant Aid Procedures

The Japanese Grant Aid is supplied through following procedures :

- Preparatory Survey
 - The Survey conducted by JICA
- Appraisal & Approval
 - Appraisal by the GOJ and JICA, and Approval by the Japanese Cabinet
- Authority for Determining Implementation
 - The Notes exchanged between the GOJ and a recipient country
- Grant Agreement (hereinafter referred to as "the G/A")
 - Agreement concluded between JICA and a recipient country
- Implementation
 - Implementation of the Project on the basis of the G/A

2. Preparatory Survey

(1) Contents of the Survey

The aim of the Preparatory Survey is to provide a basic document necessary for the appraisal of the Project made by the GOJ and JICA. The contents of the Survey are as follows:

- Confirmation of the background, objectives, and benefits of the Project and also institutional capacity of relevant agencies of the recipient country necessary for the implementation of the Project.
- Evaluation of the appropriateness of the Project to be implemented under the Grant Aid

Scheme from a technical, financial, social and economic point of view.

- Confirmation of items agreed between both parties concerning the basic concept of the Project.
- Preparation of a basic design of the Project.
- Estimation of costs of the Project.

The contents of the original request by the recipient country are not necessarily approved in their initial form as the contents of the Grant Aid project. The Basic Design of the Project is confirmed based on the guidelines of the Japan's Grant Aid scheme.

JICA requests the Government of the recipient country to take whatever measures necessary to achieve its self-reliance in the implementation of the Project. Such measures must be guaranteed even though they may fall outside of the jurisdiction of the organization of the recipient country which actually implements the Project. Therefore, the implementation of the Project is confirmed by all relevant organizations of the recipient country based on the Minutes of Discussions.

(2) Selection of Consultants

For smooth implementation of the Survey, JICA employs (a) registered consulting firm(s). JICA selects (a) firm(s) based on proposals submitted by interested firms.

(3) Result of the Survey

JICA reviews the Report on the results of the Survey and recommends the GOJ to appraise the implementation of the Project after confirming the appropriateness of the Project.

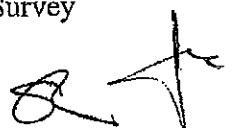
3. Japan's Grant Aid Scheme

(1) The E/N and the G/A

After the Project is approved by the Cabinet of Japan, the Exchange of Notes (hereinafter referred to as "the E/N") will be signed between the GOJ and the Government of the recipient country to make a pledge for assistance, which is followed by the conclusion of the G/A between JICA and the Government of the recipient country to define the necessary articles to implement the Project, such as payment conditions, responsibilities of the Government of the recipient country, and procurement conditions.

(2) Selection of Consultants

In order to maintain technical consistency, the consulting firm(s) which conducted the Survey



will be recommended by JICA to the recipient country to continue to work on the Project's implementation after the E/N and G/A.

(3) Eligible source country

Under the Japanese Grant Aid, in principle, Japanese products and services including transport or those of the recipient country are to be purchased. When JICA and the Government of the recipient country or its designated authority deem it necessary, the Grant Aid may be used for the purchase of the products or services of a third country. However, the prime contractors, namely, constructing and procurement firms, and the prime consulting firm are limited to "Japanese nationals".

(4) Necessity of "Verification"

The Government of the recipient country or its designated authority will conclude contracts denominated in Japanese yen with Japanese nationals. Those contracts shall be verified by JICA. This "Verification" is deemed necessary to fulfill accountability to Japanese taxpayers.

(5) Major undertakings to be taken by the Government of the Recipient Country

In the implementation of the Grant Aid Project, the recipient country is required to undertake such necessary measures as Annex-3.

(6) "Proper Use"

The Government of the recipient country is required to maintain and use properly and effectively the facilities constructed and the equipment purchased under the Grant Aid, to assign staff necessary for this operation and maintenance and to bear all the expenses other than those covered by the Grant Aid.

(7) "Export and Re-export"

The products purchased under the Grant Aid should not be exported or re-exported from the recipient country.

(8) Banking Arrangements (B/A)

a) The Government of the recipient country or its designated authority should open an account under the name of the Government of the recipient country in a bank in Japan (hereinafter referred to as "the Bank"). JICA will execute the Grant Aid by making payments in Japanese yen to cover the obligations incurred by the Government of the recipient country or its designated authority under the Verified Contracts.

b) The payments will be made when payment requests are presented by the Bank to JICA under



an Authorization to Pay (A/P) issued by the Government of the recipient country or its designated authority.

(9) Authorization to Pay (A/P)

The Government of the recipient country should bear an advising commission of an Authorization to Pay and payment commissions paid to the Bank.

(10) Social and Environmental Considerations

A recipient country must carefully consider social and environmental impacts by the Project and must comply with the environmental regulations of the recipient country and JICA socio-environmental guidelines.

(End)



Major Undertakings to be taken by Each Government

NO	Items	To be covered by the Grant	To be covered by Recipient side
1	To bear the following commissions to a bank of Japan for the banking services based upon the B/A		
	1) Advising commission of A/P		•
	2) Payment commission		•
2	To ensure prompt unloading and customs clearance at the port of disembarkation in recipient country		
	1) Marine(Air) transportation of the products from Japan to the recipient country	•	
	2) Tax exemption and custom clearance of the products at the port of disembarkation		•
	3) Internal transportation from the port of disembarkation to the project site	•	
3	To accord Japanese nationals whose services may be required in connection with the supply of the products and the services under the verified contract such facilities as may be necessary for their entry into the recipient country and stay therein for the performance of their work		•
4	To exempt Japanese nationals from customs duties, internal taxes and other fiscal levies which may be imposed in the recipient country with respect to the supply of the products and services under the verified contract		•
5	To maintain and use properly and effectively the facilities constructed and equipment provided under the Grant Aid		•
6	To bear all the expenses, other than those to be borne by the Grant Aid, necessary for the transportation and installation of the equipment		•

(B/A: Banking Arrangement, A/P: Authorization to pay, N/A: Not Applicable)

(2) Explanation of Draft Outline Design

MINUTES OF DISCUSSIONS
PREPARATORY SURVEY (3) ON THE PROJECT FOR
BREAST CANCER SCREENING AND PREVENTION CAPACITY IMPROVEMENT
IN THE REPUBLIC OF SERBIA
(EXPLANATION ON THE DRAFT REPORT)

From October to November 2009, the Japan International Cooperation Agency (hereinafter referred to as "JICA") dispatched a Preparatory Survey (2) on the Project for Breast Cancer Screening and Prevention Capacity Improvement (hereinafter referred to as "the Project") to the Republic of Serbia (hereinafter referred to as "Serbia"). Through discussions, field survey, and technical examination of the results of the survey in Japan, JICA prepared a draft report of the survey.

In order to discuss the components of the draft report with the concerned officials of the Government of Serbia, JICA sent to Serbia the Draft Report Explanation Team (hereinafter referred to as "the Team"), which is headed by Mr. Satoru Kurosawa, Chief Representative, JICA Balkan Office, from March 7 to March 14.

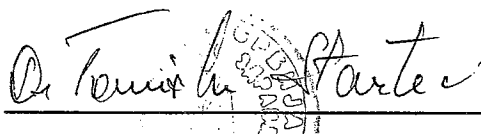
As a result of discussions, both sides confirmed the main items described on the attached sheets.

Beograd, March 12, 2010



Mr. Satoru Kurosawa

Leader
Draft Report Explanation Team
Japan International Cooperation Agency
Japan



MSc Tomislav Stantic / MD

State Secretary
Ministry of Health
The Republic of Serbia

ATTACHMENT

1. Components of the Draft Report

The Serbian side agreed and accepted in principle the components of the draft report explained by the Team.

2. Japan's Grant Aid Scheme

The Serbian side understood the Japan's Grant Aid Scheme and the necessary measures to be taken by the Government of Serbia as explained by the Team and described in Annex-3 and Annex-4 of the Minutes of Discussions signed by both sides on November 18, 2009.

3. Cost Estimation

Both sides agreed that the Project Cost Estimation, as attached in Annex-3, should never be duplicated or released to any third parties before the signing of all the Contract(s) for the Project.

4. Schedule of the Project

JICA will complete the final report in accordance with the confirmed items and send it to the Serbian side by the end of March 2010.

5. Confidentiality of the Project

Both sides confirmed that all information related to the Project including detailed specifications of the equipment and other technical information shall not be released to any outside party before the signing of all the Contract(s) for the Project.

6. Other Relevant Issues

6-1. Project Sites

The both sides agreed to the Project Sites, which are shown in Annex-1.

6-2. Project Equipment

The both sides agreed to the contents of the medical equipment which were listed in Annex-2 and would be procured in the Project.

6-3. Undertakings of the Serbian Side

The Serbian side agreed to secure and allocate the necessary budget for undertakings to be done on timely manner, based on the provisional amount shown in the draft report.

6-4. Preparatory Work for the Installation of the Medical Equipment

The Serbian side reconfirmed the preparatory work to renovate and/or improve the appropriate X-ray protection rooms to meet the Serbian regulation and remove the unnecessary existing equipment before the installation of the medical equipment. The Serbian side will also prepare proper reading rooms.



6-5. Tax Exemption and Customs Clearance of the Medical Equipment

The Serbian side reconfirmed to exempt the import tax and other relevant taxes of the medical equipment to be procured. The Serbian side agreed to coordinate with the other relevant authorities in order to ensure the smooth customs clearance, in case of the delay in the procedure.

6-6. Trainings of Radiologists and Radiographers

The Serbian side reconfirmed to conduct necessary trainings of radiologists and radiographers before the installation of the medical equipment as attached in Annex-5.

6-7. Operation and Maintenance of the Medical Equipment

The Serbian side agreed to take necessary measures for appropriate operation and maintenance of the medical equipment.

6-8. Budgets and Workforce to Implement the Screening

The Serbian side agreed to secure and allocate the budgets and workforce enough to implement the breast cancer screening program, and set the item for breast cancer screening in the Health Fund as shown in Annex-3.

6-9. Quality Control

The Serbian side agreed to establish the system on quality control of mammographic screening in cooperation between Working Group for the National Breast Cancer Prevention Program and Institute of Nuclear Sciences "Vinca" under the coordination of National Cancer Secretariats, and to take necessary measures to improve the quality control.

6-10. Soft Component Program

Both sides agreed to implement a soft component program of Japan's Grand Aid, regarding quality control of mammographic screening. Both sides also agreed the contents and necessary measures to implement the program as shown in the draft report.

6-11. Donor Coordination

The Serbian side reconfirmed the coordination among the donors to avoid the duplication of the medical equipment and to promote harmonization. Both sides understood that the breast cancer screening system in Serbia would consist of the existing medical equipment, the medical equipment procured in the Project and the other donors' assistance, and agreed to regard the synergism among them.

6-12. Treatment of Breast Cancer

The Serbian side agreed to improve medical treatment of breast cancer in order to meet the demands of the breast cancer cases detected by the screening.



Annex-1 Project Sites

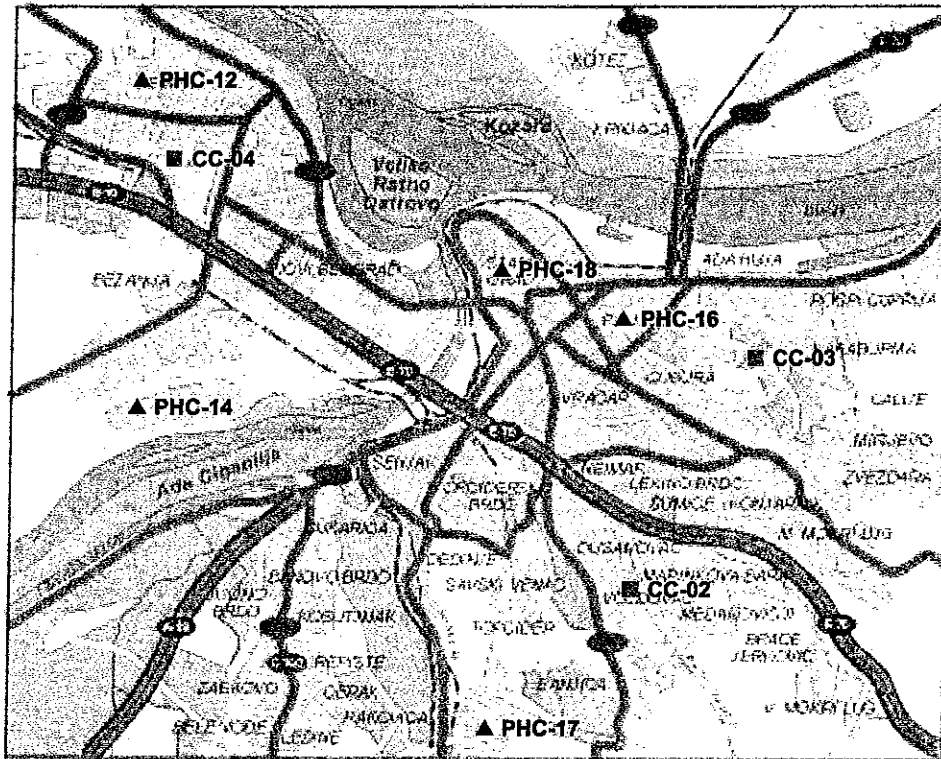
Annex-2 Project Equipment

Annex-3 Cost Estimation

Annex-4 Schedule

Annex-5 Training Plan of Radiologists and Radiographers

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Project Sites (Beograd City)

- Clinical Center (CC) (3 Facilities)
- ▲ Primary Health Centers (PHC) (5 Facilities)

Beograd

- ▲ PHC-12: Zemun
- ▲ PHC-14: Novi Brograd
- ▲ PHC-16: Pallula
- ▲ PHC-17: Rakovica
- ▲ PHC-18: Stari Grad
- CC-02: Dr Dragisa Misovic-Dedinje
- CC-03: Zvezdara
- CC-04: Zemun

Project Sites (In Beograd City)



Project Sites (Out of Beograd City)

Confidential

Annex-3

Cost Estimation

The total project cost necessary to implement this Project is estimated at

The costs to be borne by both Governments, Japan and the Republic of Serbia based on the scope of works for both Governments as described in the draft report of the Preparatory Survey (2) and respective details are estimated as follows on the conditions shown in (3) below. However, this cost estimate is provisional and would be further examined by the Government of Japan for the approval of the Grant.

(1) Cost borne by the Government of Japan

Total Cost: approximately

Medical equipment for breast cancer screening is improved.

Item	Roughly Estimate Cost (Million Yen)
Equipment Total	
Consultant Fee Total	

(2) Cost borne by the Government of the Republic of Serbia

Total Cost: approximately 122.6 Million Serbian Dinar (RSD)
(approximately 175.9 Million Yen)

- 1) Operation and Maintenance Cost: approx. 115.9 Million RSD (approx. 166.2 Million J. Yen)
- 2) Facility Renovation cost : approx. 6.2 Million RSD (approx. 9.0 Million J. Yen)
- 3) Payment Commission : approx. 0.5 Million RSD (approx. 0.7 Million J. Yen)
- 4) A/P Advising Commission : approx. 0.009 Million RSD (approx. 0.012 Million J. Yen)

(3) Conditions in Cost Estimate

- 1) Time of Cost Estimate : April 2009
- 2) Exchange Rate : 1 US Dollar = 95.03 Japanese Yen, 1 Euro = 135.24 Yen
1 Serbian Dinar (RSD) = 1.4343 Japanese Yen
1 Serbian Dinar (RSD) = 94.29 Euro
- 3) Procurement Period: 15 months, including the plan of Soft Component
- 4) Cost Estimate is implemented in accordance with the Guideline of Japan's Grant Aid.



Tentative Projects' Implementation Schedule after conclusion of the Exchange of Notes (E/N) and the Grant Agreement (G/A)

Stage	No. of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Tender and Tender related Works		<p>4 Months</p> <p>■ Detailed Design</p> <p>□ Preparation of Tender Documents</p> <p>■ Confirmation of Tender Documents</p> <p>□ Tender Announcement</p> <p>■ Bidding, Evaluation and Contract with the Successful Tenderer</p>														
Equipment Procurement and Installation		<p>8 Months</p> <p>Equipment Manufacturing □</p> <p>Transportation □</p> <p>Installation ■</p> <p>Training, Handing Over ■</p>														
Soft Component		<p>Producing QC Manual □</p> <p>Submission of Final Report ●</p> <p>Workshop and Seminar ■</p>														

Training Plan of Radiologists and Radiographers for the Project

No	Health Facility	Training Plan of Radiologist(s)	Training Plan of Radiographer(s)	
1	CC-01	CC Nis	31/05/2010-23/07/2010	03/05/2010-28/05/2010
2	CC-02	CHC, Dr Dragisa Misovic	training is finished in 2009	training is finished in 2009
3	CC-03	CHC Zvezdara	training is finished in 2009	training is finished in 2009
4	CC-04	CHC Zemun	01/04/2010-28/05/2010	01/04/2010-30/04/2010
5	HC-01	GH Subotica	26/07/2010-17/11/2010	31/05/2010-25/06/2010
6	HC-02	HC Senta	20/09/2010-12/11/2010	06/09/2010-01/10/2010
7	HC-03	HG Sombor	31/05/2010-23/07/2010	03/05/2010-28/05/2010
8	HC-04	HC Valjevo	training is finished in 2009	training is finished in 2009
9	HC-05	HC Smederevo	26/07/2010-17/11/2010	31/05/2010-25/06/2010
10	HC-06	HC Petrovac	01/04/2010-28/05/2010	01/04/2010-30/04/2010
11	HC-08	HC Negotin	15/11/2010-07/01/2011	04/10/2010-29/10/2010
12	HC-09	GH Cuprija	20/09/2010-12/11/2010	06/09/2010-01/10/2010
13	HC-10	HC Kladovo	26/07/2010-17/11/2010	31/05/2010-25/06/2010
14	HC-11	HC Knjazevac	15/11/2010-07/01/2011	04/10/2010-29/10/2010
15	HC-12	HC Zajecar	01/04/2010-28/05/2010	01/04/2010-30/04/2010
16	HC-13	HC Uzice	31/05/2010-23/07/2010	03/05/2010-28/05/2010
17	HC-15	GH Gorji Milanovac	15/11/2010-07/01/2011	04/10/2010-29/10/2010
18	HC-16	HC Kraljevo	training is finished in 2009	training is finished in 2009
19	HC-17	HC Krusevac	20/09/2010-12/11/2010	06/09/2010-01/10/2010
20	HC-18	HC Aleksinac	26/07/2010-17/11/2010	31/05/2010-25/06/2010
21	HC-19	HC Pirot	31/05/2010-23/07/2010	03/05/2010-28/05/2010
22	HC-20	GH Leskovac	15/11/2010-07/01/2011	04/10/2010-29/10/2010
23	HC-22	GH Sremska Mitrovica	01/04/2010-28/05/2010	01/04/2010-30/04/2010
24	PHC-02	DZ Zdravlja Novi Becej	31/05/2010-23/07/2010	03/05/2010-28/05/2010
25	PHC-03	DZ Mali Idjos	20/09/2010-12/11/2010	06/09/2010-01/10/2010
26	PHC-04	DZ Novi Sad	01/04/2010-28/05/2010	01/04/2010-30/04/2010
27	PHC-06	DZ Bogatic	15/11/2010-07/01/2011	04/10/2010-29/10/2010
28	PHC-07	DZ Kragujevac	26/07/2010-17/11/2010	31/05/2010-25/06/2010
29	PHC-08	DZ Trstenik	31/05/2010-23/07/2010	03/05/2010-28/05/2010
30	PHC-09	DZ Nis	01/04/2010-28/05/2010	01/04/2010-30/04/2010
31	PHC-10	DZ Bujanovac	20/09/2010-12/11/2010	06/09/2010-01/10/2010
32	PHC-11	DZ Grocka	15/11/2010-07/01/2011	04/10/2010-29/10/2010
33	PHC-12	DZ Zemun	20/09/2010-12/11/2010	06/09/2010-01/10/2010
34	PHC-13	DZ Lazarevac	15/11/2010-07/01/2011	04/10/2010-29/10/2010
35	PHC-14	DZ Novi Beograd	26/07/2010-17/11/2010	31/05/2010-25/06/2010
36	PHC-15	DZ Obrenovac	20/09/2010-12/11/2010	06/09/2010-01/10/2010
37	PHC-16	DZ Palilula	31/05/2010-23/07/2010	03/05/2010-28/05/2010
38	PHC-17	DZ Rakovica	01/04/2010-28/05/2010	01/04/2010-30/04/2010
39	PHC-18	DZ Stari Grad	26/07/2010-17/11/2010	31/05/2010-25/06/2010

Training will be realization in Institute for oncology and radiology of Serbia in Belgrade, Institute for oncology in Sremska Kamenica and Clinical Centre Nis.

5. Soft Component (Technical Assistance) Plan

This Project will be implemented to procure mammography units and its related equipment for the 39 health facilities planned for equipment installation and it is expected to drastically improve the breast cancer screening services of those facilities. To maintain the high operability of the procured equipment in an appropriate manner, however, it is necessary to reinforce the quality control of the equipment. For this purpose, soft components are recommended in consideration of the following points:

(1) Background to planning soft components

The Project for Breast Cancer Screening and Prevention Capacity Improvement is intended to install equipment for use in breast cancer screening services in 39 health facilities.

When operating the mammography unit, it is necessary to obtain high-resolution, high-contrast images of high quality with a low dose. To attain this effect, it is essential to use the radiography equipment at the performance required for mammography unit (hereinafter called “the Equipment”), to optimize the technical factors including the radiographic conditions, receiving system, developing process and removal of scattered radiation, and skill factors such as positioning and compressing the breasts, and to draw up and implement a total quality assurance program for these factors.

The Committee Members of the Working Group for the National Program for Prevention of Breast Cancer, also recognized that mammography in Serbia, especially in local health facilities, has not yet reached the appropriate level in radiographic positioning and quality of mammograms. Therefore, reinforcement of the technical ability of radiologists and radiographers are called for. It is very important and significant to improve the technology in quality control of mammographic images and equipment accuracy control in Serbia in order to build the foundations of the breast cancer screening system in Serbia. It is also important to support the establishment of the breast cancer screening system and continuous use of the medical equipment to be procured in the Grant Aid Project with appropriate accuracy, by making use of the soft components provided by Japanese consultant.

(2) Goal of soft components

The soft component is aimed at technical improvement in image control of the radiographs and in quality / accuracy control of the mammography in order to realize appropriate and effective use of the procured medical equipment. In particular, manuals for the daily maintenance procedures for the mammography and X-ray film processor that the radiographers will operate daily will be prepared in order to maintain the appropriate image

quality of the radiographs, and training using the manuals will be furnished to improve the skills of the radiographers. These activities will be the first step toward standardizing the screening work by mammography and quality control work in Serbia in future.

(3) Outputs of soft components

The soft component will be introduced as a quality control tool for the radiographs and quality / accuracy control tool for the mammography unit and X-ray film processor by preparing the manuals for such equipment. A maintenance system and structure (including personnel) will be established by appointing a radiographer as the person responsible for quality / accuracy control and the equipment users, and quality / accuracy control will be reinforced at the same time.

(4) How to measure the outputs from the soft components

The procedure for measuring the effect attainability of the soft components is as follows:

- 1) Prepare a quality control manual for the radiographs (radiographic images) and quality / accuracy control manuals for the mammography unit and X-ray film processor.
- 2) Prepare a guide for daily maintenance and operation in which the workshop participants make entries for quality control and accuracy control (a set of forms for recording entries)

(5) Plan of soft component activities (input plan)

The soft component activities will include the preparation of quality and accuracy control manuals, and workshops and on-the-job training using the manuals, which are described in detail below.

1) Preparation of manuals

In response to the results of the bidding for procurement of the medical equipment, “Accuracy Control and Quality Control Manuals” for the procured equipment (mammography unit and X-ray film processor) (as shown in Table 2.4 herein) will be prepared in Japan and submitted to the working group for the National Breast Cancer Screening and Prevention Program in Serbia for approval.

2) Workshop

The workshop will be held for 3 days after the procured equipment is handed over to the Serbian side (one day each for explanation of the mammography unit, X-ray film

processor, and positioning for radiography). As there are as many as 39 facilities in this Project, the target sites will be divided into 3 groups in the northern, central and southern areas and the same 3-day workshop will be held at a central location (site) in each area. The workshops will be held using the prepared accuracy control and quality control manuals.

For these workshops, two Japanese consultants will be dispatched (accompanied by a translator). In each workshop, explanations will be given of the accuracy / quality control procedures for the mammography unit and X-ray film processor and the operating procedures of the inspection equipment for use in the accuracy control process (various types of phantom for use in inspection of the mammograms, and a sensitometer and densitometer for use in inspection of the X-ray film processor), and on the positioning method for radiography.

3) On-the-job training

Following each workshop as described above, on-the-job training will be provided in the same operation scheme. In the on-the-job training, the procured equipment will be operated first in a demonstration by the instructors, followed by a return demonstration by the participants in the workshop. As there will be many participants, this type of training will be provided for 2 days each at the above 3 facilities (in the northern, central and southern areas) taking into consideration the fact that all the participants can join the training. The two Japanese consultants will answer questions posed by the participants and check whether they can operate the procured equipment properly and whether they can operate the inspection equipment related to accuracy control.

4) Personnel plan (by Japanese consultant)

Two engineers will be dispatched to take care of the fields as described in Table 2.4 “Outline of Accuracy Control and Quality Control Manual for mammography unit and X-ray film processor,” in which they will prepare the manual and provide the workshops and on-the-job training. In this case, one engineer will be in charge of translation and administration of the manual, including binding.

Engineer 1: Technical quality / accuracy control of mammography unit and X-ray film processor (one person)

Activities (Items 1 to 3 in Table 1 below)

- Preparation of quality / accuracy control manual (including translation into Serbian)
- Holding and operation of workshops and on-the-job training

Engineer 2: Instruction in quality control of radiographic images and image interpretation environment (one person)

Activities (Items 4 to 7 in Table 1 below)

- Preparation of accuracy control and quality control manual (Japanese)
- Holding and operation of workshops and on-the-job training

Table 1 Outline of Quality and Accuracy Control Manual (draft)

<Importance of Quality Control>
<p>In order to secure a satisfactory level of mammography in screening mammography, it is essential to conduct appropriate periodical maintenance of the equipment and devices as well as quality control of the images. It is important for the screening staff at the facilities to understand and implement proper quality control measures in order to achieve successful screening mammography. Radiological technologists are required not only to improve their image-taking techniques but also to study how to maintain the image-taking devices and the quality of the images.</p> <p>In Japan, the “Mammography Quality Control Manual” (prepared in line with the mammography quality control manual of the American College of Radiology (ACR)), “Mammography Guidelines” and “Guidebook of Breast Cancer Screening” are essential reference books. Radiological technologist qualifications for screening mammography are given to persons who have passed the written and image analysis examinations (by separate category, with a pass level of 70% out of a total 300 points) after participating in 2-day technical lectures for radiological technologists held by the Central Committee on Quality Control of Mammographic Screening, a non-profit organization, on background, morbidity of breast cancer in Japan, mortality, the necessity of early detection to reduce deaths by breast cancer, the breast cancer screening system, and the basics of mammography (image engineering, image evaluation, equipment maintenance, pathology, dissection and image-taking techniques, etc.). The number of qualified radiological technologists was more than 8,000 as of 2007.</p> <p>During the seminar, participants learn about the difficulties of mammography, why management of equipment is necessary, how to maintain the equipment, etc., and formulate manuals for practical purposes.</p>

Item 1 Radiation Quality and Dose

Factors that affect the quality of radiation: tube voltage, targeted material, filter material

It is important to maintain a balance between image quality and exposure.

(1) Tube Voltage

Ordinary image-taking by X-ray is performed with a tube voltage of around 25 to 32 kV. The slightest variation in tube voltage affects the contrast and/or exposure. Check the correctness of the displayed tube voltage using a tube voltmeter.

(2) Radiation Quality

In order to achieve high contrast visualization of the inside of the breast which absorbs X-rays evenly, low LET radiation is used. Normally, Mo anodes that create X-rays with 17.5keV($k\alpha$) and 19.6keV($k\beta$) characteristics, and Be (*Beryllium*) are used for the radiation port in order to extract these particular X-rays effectively. In order to remove the element of low LET radiation that is absorbed in the breast and does not cause color change of the film from X-rays created using Mo, Mo filters with a thickness of 0.03mm are used. To investigate thicker breasts and/or breasts with high mammary gland density, Mo/Rh (Mo target, Rh filter) is used. It should be noted that the energy spectrum will be influenced by the combination of anode material and filter.

(3) Measuring Radiation Quality (Half-Value Layer)

Al plate with high purity (99.9% or higher) is used ··· measurement method Permissible range of half-value layer

(4) In-air Exposure

Radiate the X-ray on the breast phantom (RMI Type156) (fat 50%, mammary gland 50%) using AEC, and measure the in-air exposure at the height of the upper surface of the phantom.

(5) Average Mammary Gland Dose

Use the tube voltage, half-value layer, and in-air exposure values. Obtain the converted value from the table created using the tube voltage value and half-value layer as the parameters, and then multiply it by the in-air exposure value in order to obtain the average mammary gland dose.

IAEA (International Atomic Energy Agency) : The upper limit of the average mammary gland dose per exposure on a breast with a thickness of 42mm is 3mGy (1.7 to 2.0mGy is the standard range in Japan). Influential factors are the combination of screen/film, the X-ray equipment, automatic film processing equipment, etc.

Item 2 Image-taking Equipment and Maintenance

(1) Loss on Chest Wall (confirmation of position of focal point)

- Confirm the position of the focal point of the X-ray tube in order to minimize image loss on the side of the chest wall.

- Confirm the geometrical position of the chest wall edge on the film.

- Judgment criteria: IEC 61223-2-10 "there shall be no loss greater than 6mm from the examinee's chest wall edge at a position 2.5mm from the upper surface of a compressed breast with a thickness of 45mm". Confirm it with the iron dot image.

(2) Performance of Focal Point (Resolving Power Chart Method) (only for S/F system)

High resolving power is required for taking breast X-ray images in order to visualize very small symptoms such as microscopic calcification or tumors, and the size of the X-ray focal point is very important.

The rectangular resolving power chart method is described in IEC61223-2-10 as the method to evaluate the size of the focal point.

- Width of focal point (set horizontally to the pattern axis of the chart): more than 13L/mm

- Length of focal point (set vertically to the pattern axis of the chart): more than 11L/mm

(3) Evaluation of AEC (Automatic Exposure Control) Performance

Characteristics of the exposed object, tube voltage, and reproducibility

(4) Compressing Device

Foot switch, accuracy of compressing pressure

Item 3 Processing / Developing Process

(1) The screen/film for taking breast images by X-ray is characterized by high sensitivity and contrast in order to visualize the image by transforming the slightest difference in the level of absorption of the X-rays by the breast tissue into a difference in film density. Strict management of the developing process is essential since there is little latitude and even a hint of change in the image characteristics would influence the quality of the image.

(2) Cleaning and Tidying of Darkroom

If dust gets between the screen and the film, a shadow characterized as calcification and artifact will occur. The darkroom must be kept clean and free of dust.

The air-conditioner outlets, safety lights, film-inserting table of the automatic processing equipment, and worktable must be cleaned every day.

(3) Purpose and Management of Automatic Processing Equipment

Measure the density (D) at each step by processing ordinarily exposed test pieces.

- Fog Density

- Sensitivity : The benchmark is "the closest density step to D 1.2"

- Contrast

The density difference is obtained by extracting the closest density step higher than 0.45 from the closest density step lower than 2.20.

- Targeted density: fog density ± 0.03 , sensitivity ± 0.15 , contrast ± 0.15

(4) Fixation on Film

If the film is not properly cleaned with water and hypo remains, it will change color to yellowish brown during long-term storage. A residue hypo test must be performed.

(5) Periodical Replacement of Developer and Fixing Solution in Automatic Processing Equipment

- The developer and fixing solution should be periodically replaced every 2 to 3 months.

- The crossover rack, etc. must be cleaned every day.

Item 4 Manner of Image-taking

(1) How to deal with examinee

- Reception

Manners as a medical officer, communication skills and human skills are important.

- Briefing on screening and advice when taking image

Explain that the examinee's breast will be compressed and it will cause a certain amount of pain and therefore you must request the examinee's cooperation.

- Keep examinee's privacy in mind

Consider the examinee's sense of embarrassment

(2) How to take images

- MLO (Medio Lateral Oblique)

- CC (Cranio-caudal)

Satisfy the image-taking conditions.

Item 5 Management of Images

(1) Factors that Influence Image Quality

When an artefact is observed, judge the cause.

Breast X-ray equipment, screen/film, automatic processing equipment, examinee

(2) Evaluation as Total System

- Normal functioning of the X-ray equipment and automatic processing equipment must be confirmed every time before use.
- Take an image of the breast phantom for image evaluation (156 phantom), and set the AEC as the density at the centre of the phantom comes into the range of 1.5 ± 0.15 (S/F system) or 1.5 ± 0.1 (CR system). (In case of clinical images, the appropriate mammary gland density is 1.2 to 1.59 and the standard image-taking condition is when the density of the 156 phantom becomes 1.7 to 1.9.) The permissible density for the CR system is rather strict at 1.5 ± 0.1 .
- Confirm that the visualizing ability of the imitation materials such as the fiber structure, calcification and tumors in the phantom is better than the evaluation benchmark.

Item 6 Image Analysis Environment

(1) X-ray film viewer

To use the schaukasten exclusively for breasts: luminance is expected to be over $3,500 \text{cd/m}^2$
External light on the film should be masked.

(2) Illuminance of X-ray film reading room

It is advisable that the illuminance near the schaukasten in the room where the mammogram is to be analyzed is less than 50lx.

Item 7 Evaluation of Clinical Images**(1) Image Quality**

Mammary gland density (1.2 to 1.59), the maximum density of the film should be more than D max 4.0, and it must have fine contrast, film grain, and sharpness.

(2) Positioning

Positioning and compression must be appropriate and must satisfy the image-taking criteria of MLO and CC image-taking.

(3) X-ray field, image-taking information, film mark, etc.**- Digital Mammography**

At present, analogue (S/F) accounts for 30% while digital accounts for 70% (of which CR accounts for 90% and DR (FPD) 10%) in Japan and transition of the system to digital is in rapid process.

- Characteristics of the digital system:

- Wide dynamic range
- Images can be processed.
- Images can be displayed in real-time.
- Data can be easily stored.
- Network diagnosis system is possible.
- CAD (Computer Aided Diagnosis)

Item 8 Proposed Form of Data Recording for Quality Control

(1) Daily quality control : Cleaning of operating room, cleaning of related devices, etc.

(2) Daily quality control : Management of automatic X-ray film processing equipment and confirmation of functioning of AEC

(3) Periodical quality control: Evaluation of phantom image

(4) Check schaukasten and fog in the darkroom.

(5) Check contact of screen and film.

(6) Evaluation of X-ray equipment

Check the functioning of the compressing device and other parts of the equipment, adjustment of the X-ray exposure field, positioning of the focal point, accuracy of the tube voltage and reproducibility.

<Conclusion>

Mammograms with extremely high image quality that achieve fine contrast, sharpness and fine grain are required for breast screening. It is necessary to continuously control the quality of the whole system, in addition to the improvement of image-taking techniques, in order to maintain mammograms that satisfy the standard image quality.

It is essential to strictly manage the automatic film processing equipment when implementing screening mammography by the screen/film (S/F) system.

It is necessary to formulate a quality control manual specifically for Serbia with reference to EUREF (European Reference Organization for Quality Assured Breast Screening and Diagnostic Services), and to manage quality control by conducting training in management together with the improvement of image-taking techniques. It is desirable that screening mammography operations and quality control be standardized in Serbia by controlling the image quality and managing the equipment in line with the uniform quality control program at the screening facilities.

(6) Resources for soft component

The Japanese Consultant will select the appropriate engineers for the above activities from the following viewpoint:

The Consultant members have twice participated in the Field Survey in Serbia and are familiar with the technical capacity of the radiographers that needs to be strengthened, and have other associated knowledge and information as well as an appropriate operation scheme at the facility sites. Therefore, the Japanese Consultant members that are expected to provide the seminars and on-the-job training in an effective and efficient way will directly support those events. Engineer 2 will be a radiographer.

(7) Implementation schedule

(Number of persons, form, time and period for each activity and term)

Two engineers will be dispatched. The work volume will be 8 hours per day/5 days per week, and the accuracy control and quality control manuals will be prepared in Japan. The workshops and on-the-job training will be held in Serbia.

