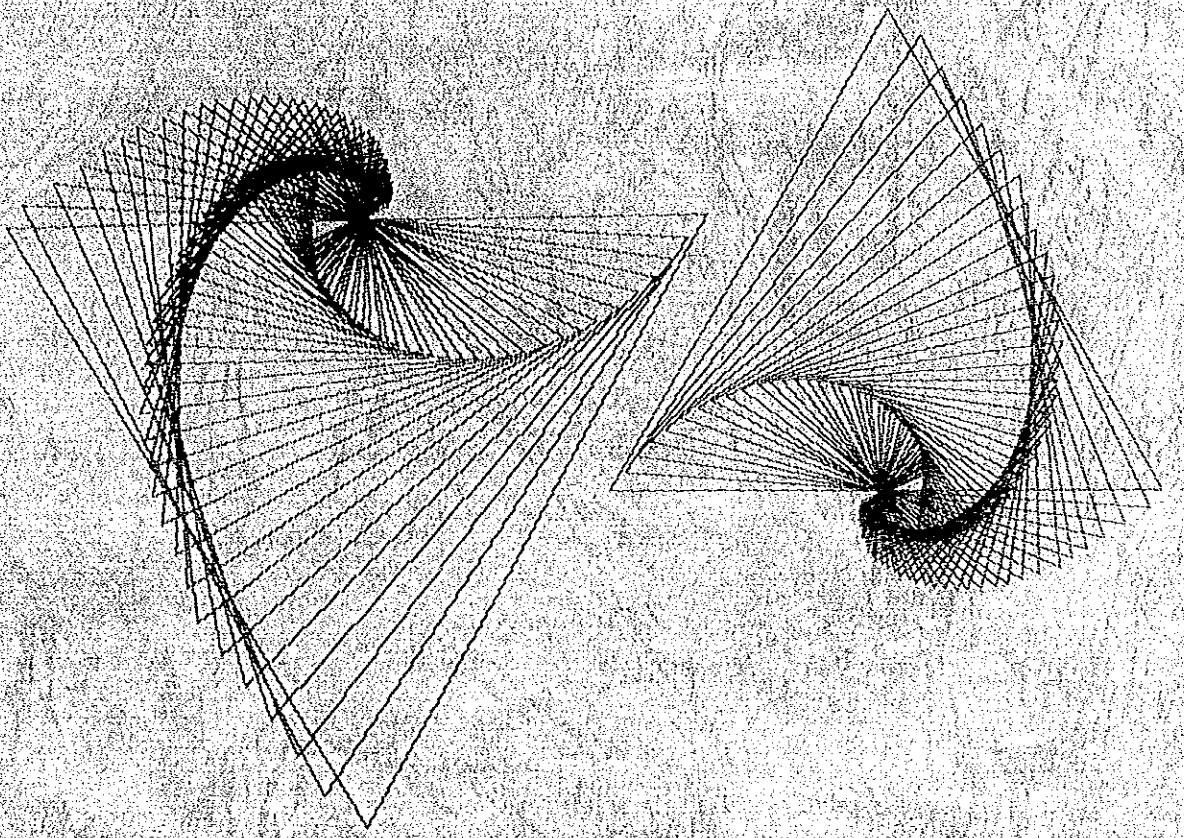
JAPANESE ENCEPHALITIS VACCINE PRODUCTION PROJECT

(INDIA)



March 1989

Institute for International Cooperation
Japan International Cooperation Agency (JICA)

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PREFACE

The Project-type Technical Cooperation is an integrated form of cooperation whose aim is to realize technology transfer to relevant personnel of the project in the recipient country, by effectively combining such assistances as dispatch of experts, training of counterparts in Japan, and supply of equipment as required. It is intended to assure smooth and systematic implementation of technical cooperation program through planning, implementation and evaluation.

The duration of cooperation is usually about five years. When the project is actually commenced, a variety of survey teams and experts are dispatched to the recipient country, preparing work reports.

This case study of Project-type Technical Cooperation has been compiled originally in Japanese, then translated into English, based upon a number of these reports prepared at each stage of planning, implementation and evaluation of the project.

We would be pleased if it would be of some usefulness as reference material for those who are interested in our technical cooperation.

March 1989

Director
Institute for International Cooperation
Japan International Cooperation Agency (JICA)

CONTENTS

Outline of the Project

To prevent widespread of Encephalitis inside the country the Indian Government planned to produce the Japanese encephalitis vaccine and requested technical cooperation from Japan since it has many years' experience in production and use of the vaccine. In March 1982, after two and a half years of deliberation, the Record of Discussions on the Project-type Technical Cooperation was drawn up and signed by the both parties.

The specific content of the technical cooperation was that Japan would provide the know-how of producing the Japanese Encephalitis Vaccine (property of Nakayama of Prevention Research Institute) in inactivated, frozen, and dried condition for the use of two million people a year in the Central Research Institute (CRI) at Kasauli for four years after the signing of the R/D, and that Japan would provide chief machinery on the basis of grant aid and technical cooperation, while the Indian Government would provide the facilities for production and other subsidiary facilities for the project.

Due to the delay in repair and maintenance of production facilities, and damage to the freeze drying machine provided on grant aid in an accident in transportation, the realization of the original project plan was thought to be impossible.

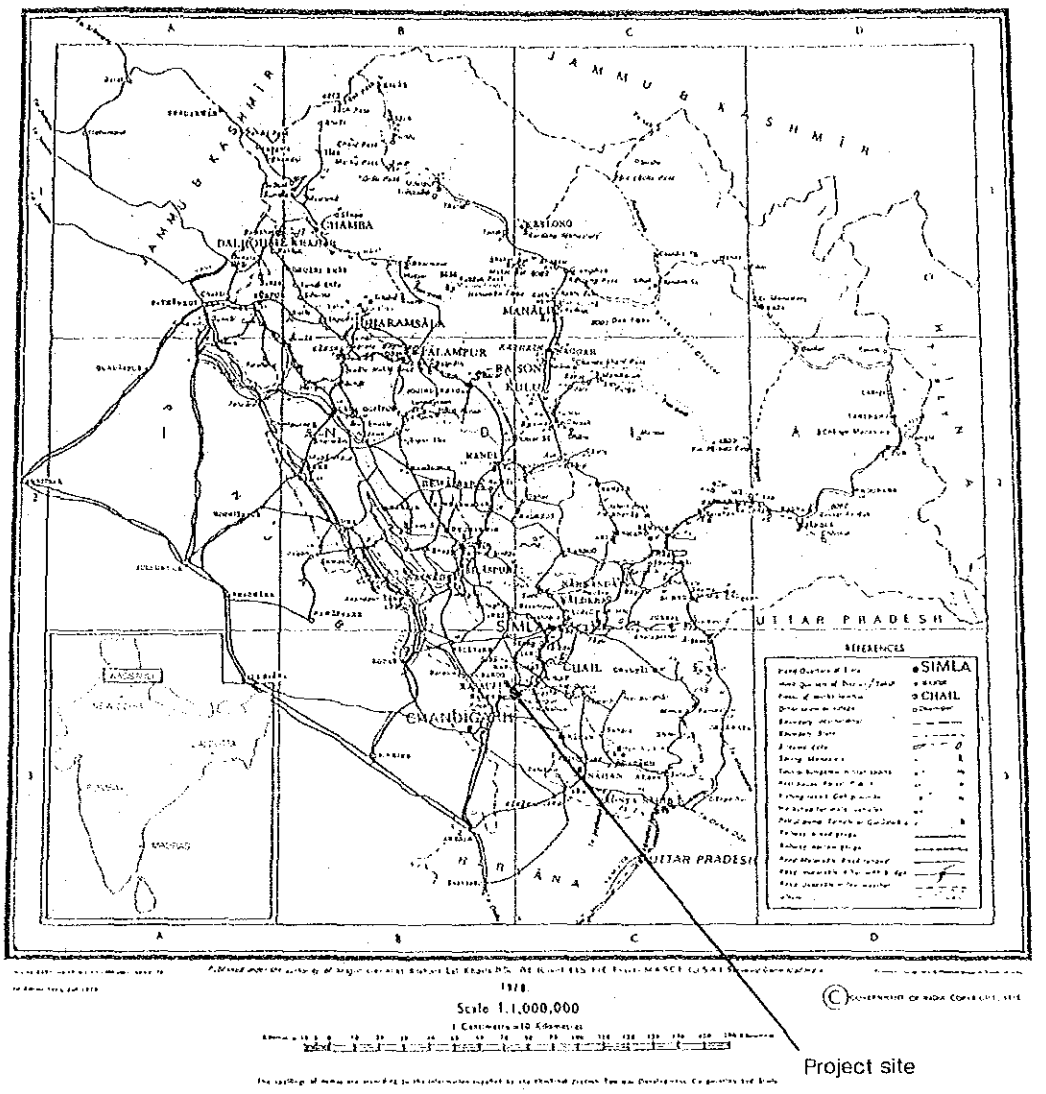
In June, 1984, the Japanese Mutual Consultation Team went to India to amend the original plan, and drew up with the Indian side a new plan to be completed within the cooperation period.

The repairing of production facilities went on in accordance with the amended plan. Transfer of production techniques was almost over, and although the repair of the freeze drying machine necessary for the final products remained unfinished, the end of the cooperation term was approaching.

In December 1985, the evaluation survey team consulted with the Indian side at the instruction of the internal committee on the Japanese side to extend the cooperation term for a year in order to produce the final products. Because it was impossible to produce the vaccine for two million people a year as aimed at in the beginning stage, an provisional activity plan was drawn up.

Thanks to the enthusiastic participation on the Indian side, final products were produced within the extended term even though the quantity of products fell short of the original plan.

Map of the Project Site



Outlined Schedule of the Project

Name of Country: India Title of Project: the Japanese Encephalitis Vaccine Production
Date of Request: October 1979, Date of Signature: March 1982, Term of R/D: March 1982-March 1986, Extended Term: March 1986-March 1987

Fiscal Year	1980	1981	1982	1983	1984	1985	1986
Connection with Grant-aid Fund Cooperation	Yes						
Dispatch of Survey Teams (No. of members) Period	Preliminary survey '81/2/10~2/19	Pre-Implementation (6) 8/28~9/6 Implementation Discussion (5) '82/3/2~3/14			Mutual/Consultation (6) 6/7~6/17	Evaluation (5) 12/9~12/20	Evaluation (5) '87/3/16~3/25
Dispatch of Experts			5/7~5/14 Grant aid Equipment Arrangement Plan	Machinery Setting Operation Instruction (2) 9/25~10/2	Experts on Short-Term Basis from 2 to 8 Weeks between October to December Machinery Setting (8) Trial Operation of Machinery (3) Vaccine Production (2) Bulk Production (2) Total Number of Dispatch (15)	4/4~4/13 Engineering 4/4~5/3 Bulk Production 4/4~5/3 Quantity Administration 5/30~6/12 Bulk Production 5/30~6/29 Bulk Production (2) 5/30~6/29 *Quality Administration*	4/15~4/20 Engineering 8/25~11/22 Production of Final Products (2) 10/13~11/23 Quality Administration (2)
Acceptance of counterpart personnel General Administration Bulk Production Quality Administration Final Product Engineering			'83/1/24 ⟷ 2/18 '83/3/19 ⟷ '84 10/1 2/25 ⟷ 5/22 9/1 ⟷ 11/30 10/11 ⟷ 11/30 '84/2/25 ⟷ 4/30 10/16 ⟷ 12/25 '84/2/25 ⟷ 5/22 '83/3/19 ⟷ 10/1			7/18 ⟷ 10/30 '86/1/7 ⟷ 3/8	'87/3/25 ⟷ 4/30

Brief History of the Project

Oct. 1979	Request for technical cooperation in Japanese Encephalia Vaccine production in India.
Feb. 1981	Dispatched of the facts-finding team
Aug. 1981	Dispatch of the preliminary survey team
Feb. 1982	Exchange of Notes signed on grant aid cooperation.
March 1982	Implementation survey team dispatch to consult about the specific content of technical cooperation with the Indian Government officials involved to prepare R/D as a result of consultation. R/D signed on the project
Feb. 1984	Dispatch of follow-up survey team for grant aid
June 1984	On receiving the report of the survey team mentioned above, mutual consultation team was dispatched for consultation on the review of the project planning. Drawing-up of a new schedule table after discussion of delay and promotion of the project
Dec. 1985	Evaluation team dispatched to evaluate the results upon completion of the project cooperation term As it was evident that attainment of the first goal was impossible within the cooperation term, it was decided that a measurement policy be established for the future. As a result of the survey, it was decided that the term be extended one year, and concrete activities were scheduled.
March 1987	Evaluation team dispatched after extention of the term, and recognition of aforementioned accomplishments. Project ended.

1. REQUEST FOR COOPERATION

1-1 Process to Request

In response to the request from the Government of India in the autumn of 1980 for cooperation in the production of vaccine, JICA decided to survey the contents of the request in detail.

To determine if technical cooperation is practical and to examine the background of the request, Dr. Otani (National Institute of Health) and three fact-finding team members were sent to India and carried out a field survey in February 1981.

The team visited the Ministry of Health of India that had planned production of the Japanese Encephalitis Vaccine, and the Ministry of Finance that supported the project financially. The team studies how the Government of India was tackling this project, and visited the Central Research Institute at Kasauli, the designated site for production, and the National Virus Research Institute at Pune, Maharashtra State, which had a great reputation for its research of the Japanese Encephalitis Vaccine.

In the survey, the team affirmed that seven states under the threat of Japanese Encephalitis had wanted its vaccine, and proposed producing vaccine for two million people a year to meet their demand. The survey team also affirmed that the Ministry of Finance of India had approved finances for investment in facilities and that the seven states were expecting the provision of necessary machinery for vaccine production and training of workers and follow-up.

When the team observed the Central Research Institute at Kasauli, it found that repair work of production facilities was proceeding based on the survey report of short-term consultants of WHO, proving the serious intent on the Indian side to carry out this project.

1-2 Establishment of Cooperative Attitude within Japan

From the report by the Fact Finding Team, the Indian Government's enthusiasm for the production of vaccine was obvious, prompting Japanese side to discuss their response to her project cooperation request.

In order to easily produce a large quantity of good quality vaccine, a special ultracentrifuge (K-II Zonal Centrifuge) was regarded as necessary. As this was a cold chain type vaccine, it did not work well under scorching climate. As such it must be a frozen, dried type, and to produce such a vaccine in great quantity, a large-sized freeze drying machine is necessary. Since such machines were not produced in India, India must buy them from foreign countries, or depend upon Japan's assistance. From the examination by vaccine production experts, roughly ¥520 million was needed to build such machinery. The Foreign Ministry of Japan agreed to share expenses for the purchase of machinery, with the Indian side, thus settling the financial aspect of the project.

At the same time, technical cooperation problems including providing the production techniques, seemed to have come to a standstill, as the scale and content of India's request was too big for the Japanese vaccine producing organizations to deal with independently.

The chief of the preliminary implementation survey team Dr. Oya, emphasized the importance of checking the cases of Japanese Encephalitis in India, and asked the Virus Pharmaceutical Corporation, a production organization of biological pharmacy, for reconsideration of India's cooperation request of this time, contending that because the vaccine was developed in Japan, Japan was in a position to give positive cooperation.

Through the Chief of the Biological Pharmacy Section, the Ministry of Health and Welfare requested that the Virus Pharmaceutical Corporation give reconsideration to India's request. The Virus Pharmaceutical Corporation summoned the managing staff of all organizations that produce the Japanese encephalitis Vaccine and examined various suggestions. As a result, it was decided that the Virus Pharmaceutical Corporation take charge of the business of technical cooperation between the seven organizations affiliated with the corporation and the National Institute of Health.

In short, a number of producing corporations would take charge of production of the vaccine, and technically therefore respond to the cooperation request from India.

2. PROJECT IMPLEMENTATION CONSULTATION

2-1 Dispatch of Implementation Survey Team

From the investigation by the Implementation Survey Team in August 1981, the important points of the cooperation request by the Indian Government and the practicalness of technical cooperation were affirmed. The pending grant-aid fund also was to be realized to purchase high-cost machinery as well as the signature of Exchange Notes (E/N).

As the conditions were set, procedures were taken for dispatch of the Implementation Survey Team, for the presentation of a project framework and technical cooperation implementation plan, consultation, drafting and signature of the Record of Discussions (R/D) with the Government of India. The five member project survey team headed by Dr. Oya went to India in March 1982, for consultation and drafting of a R/D. At the same time, the team investigated other items necessary for implementation of the project, and had sufficient discussions with the Indian officers concerned.

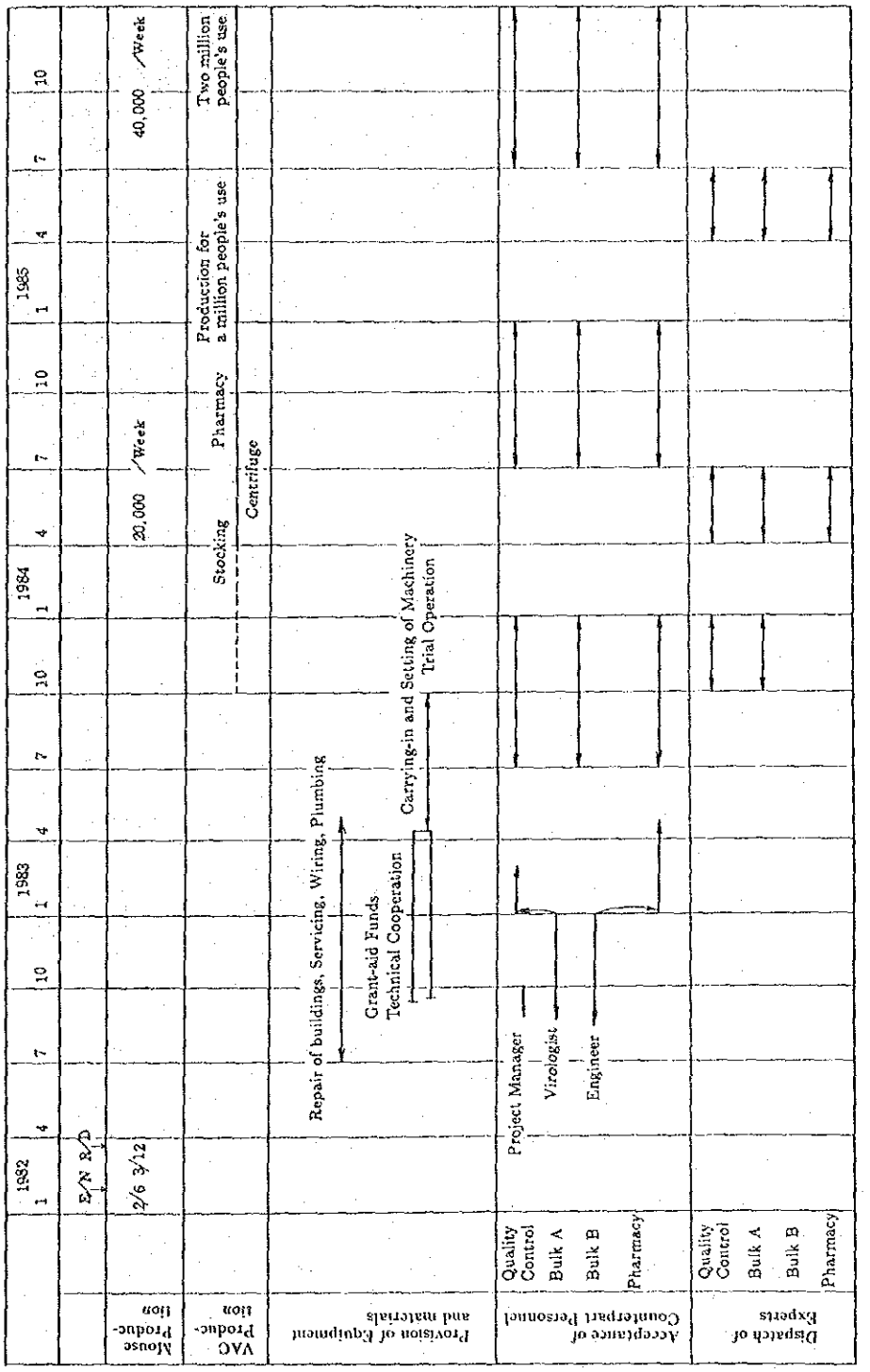
The following items were investigated and discussed:

1. The form of technical cooperation is of project-type technical cooperation including dispatch of experts, provision of equipment and materials and acceptance of counterpart personnel.
2. The term of technical cooperation is four years
3. Necessary explanation of techniques is to be made to establish the production and quality control systems suited to India, so as to enable production of two million innoculations of vaccine a year by the final year of the cooperation term.
4. Machinery to be purchased on the Indian side through grant aid cooperation is to be listed.
5. Confirmation is to be made of items of defrayment on India's part not described in the Record of Discussions (for example, reconstruction of buildings, maintenance of facilities, layout of machinery) and explanation is to be made through data-like charts from the Japanese side.
6. The Indian side must be responsible for quality testing the produced vaccine, its preservation and use, the solution of users' complaints, with notes to be exchanged on this point.
7. Vaccine production techniques are not to be transferred to a third person or a third country.
8. The production of vaccine is to be made in the Central Research Institute at Kasauli, and all responsibility concerning production of the vaccine is to be placed on the Ministry of Health and Family Welfare of the Government of the Republic of India.
9. Treatment of the dispatched experts is determined by the rules for privileges and exemptions afforded to experts dispatched under the Colombo Plan which is now stipulated and practiced by the Government of the Republic of India.
10. The committee within Japan and its sectional meetings on techniques are to be set up by the Japanese side for smooth implementation of this project.

2-2 Project Implementation Plan

With the conclusion fo the Record of Discussions, the four year term of technical cooperation was implemented from March 12 1982, and the implementation plan was drawn up (Table 1). As shown in the table, the schedule which incorporated the expected time for start-up operation of machinery provided by Grant Aid Cooperation and technical cooperation, and the time of reception of training personnel and of dispatch of experts from Japan was made up. According to the schedule, in the third year, production of the vaccine for one million people's use was scheduled, and in the final year, for two million people's use as planned.

Table-1 Technical Cooperation Implementation Plan for the Japanese Encephalitis Vaccine Production in the Republic of India



3. PROJECT IMPLEMENTATION PROCESS

3-1 Summary of Implementation Process until Dispatch of Implementation Survey Team

As described before, the Record of Discussions was concluded in March 1982, and the technical cooperation project by JICA was scheduled to begin and the Technical Cooperation Inplementation Plan was set up. However, things did not go as well as planned, and the project faced a grave setback. As such it may be necessary to describe the process summary first.

In February 1982, before the conclusion of the Record of Discussions, Grant Aid Funds were to have been provided for the purchase of high-cost machinery necessary for the project, and signatures had been affixed on the Exchange of Notes (E/N). The Japanese side urged the Indian side to pay the grant aid funds immediately through the diplomatic route, but payment on the grant aid funds did not materialize because approval had not yet been given to this project by the Economic Development Council on the Indian side.

JICA sent technical experts versed in machinery to urge payment of grant aid funds by explaining to the Indian side the necessity of the machinery and the nature of grant aid funds. Akira Yamada, one of the experts, and another official went to India in May 1982, to try to realize payment of grant aid funds by making minute explanations, but the Indian side would not consent to immediate solution because payment was not yet approved by the Economic Development Council.

It was toward the end of July of that year that the cooperation project was approved by the Economic Planning Council, and the payment from the grant aid funds was to be made six months after the signature to the Exchanged Notes.

Toward the end of October the purchase of machinery with the grant aid funds was officially recognized and the contract was concluded after procedures such as bidding. The machinery was shipped from Japan in January 1983, and arrived in Bombay in May of that year.

Two Japanese experts, Nakamura and Hara went over to the project site toward the end of September that year, the date of the Indian request, with detailed data necessary for instruction on installation of machinery. When the package of freeze drying machinery was unbundled, great damage was found, and it was determined that use of the machinery was impossible without repair work. According to the transport report, damage had occurred when the package was dropped in overland transport and while unloading at the destination.

From the report by the experts, Nakamura and Hara, the situation was found to be serious and the committee within Japan and the technical group consulted to take measures to remedy the situation.

As the close investigation into damage to the machinery took precedence over anything else, the "Grant Aid Cooperation Follow-up Team", consisting of experts Yoshizawa and others well acquainted with the machinery purchased with grant aid funds were to go over to the site in February 1984 for an investigation. The following was a brief report of the result of the investigation and examination conducted by the team.

(1) Damage of machinery and measures to be taken

Freeze Drying Machine: Damage was found everywhere on the body, doors, the heat exchanger, and refrigerator, and it was concluded that on the spot the repair was impossible. It was therefore considered a necessary measure to send all the equipment back to Edwards Co., Italy and accept it after complete repair and readjustment. But as it was estimated that the repair work would take more than one year, at about the same amount as the original cost, it was dicided to make this company deliver new articles.

K-II Zonal Centrifuge: Fortunately, this machine did not suffer much damage, so exchange of parts and repair work on the site was considered possible.

No damage was found in the other machinery. However, according to the report, the machinery had been in disuse since they were shipped in January of the previous year, and as such it was desirable to install them of the earliest possible time for trial operation.

(2) Building Repair Procedures

Repair work on the buildings for final production was almost over, but when the machinery was actually delivered, errors in construction which would hamper the work were found, and it was deemed necessary that the repair work be done again. As for JE Building, no repair work had been started.

The survey team made their damage report from the results of the survey, and handed it in including the recommendation to the Indian side to take the immediate measure of demanding claims for damage.

3-2 Dispatch of Mutual Consultation Team and Drafting of Amendment Plan

3-2-1 Implementation Survey Team Dispatch

Upon receipt of the "Grant aid Cooperation Follow-up Team Report", the committee inside Japan recognizing the seriousness of the situation, judged that it was necessary to amend the initial implementation plan made up in 1982.

According to initial planning, the preparatory work of basic arrangements such as repair of buildings, installation of equipment, and trial operation was to be completed by September 1983, and regular vaccine production was to start in April 1984. Such preparatory work was not over however, and there was no definite prospect of when vaccine production could be started. Aside from the damaged freezing and drying machine, the initial planning was delayed for one year. And the thought of the delay in installation of the freeze drying machine made them afraid that the project would come to a standstill. In order to remedy the situation, it was considered necessary to study the situation minutely by dispatching the implementation survey team, and working out a proper amendment plan.

The aims of this team were investigation and promotion of the procedures of insurance payment for the damaged equipment provided by grant aid funds, investigation and promotion of the repair process of buildings, and installation and trial operation instruction of provided machinery. Another aim through this process

was to get the production process of the interim products (bulk) under way and start production of the final products immediately after installation of the freeze drying machine.

With these things in mind, the Mutual Consultation Team went to India in June 1984 to discuss the measures of solving and promoting the pending problems with the Indian side, and to make up a new schedule.

The following was an itemized description of the results of investigation and cosultation.

(1) Repair of building and installation of facilities

The working places for producing bulk and final products were each situated in separate houses, and repair work on the working places for producing final products was almost completely finished, according to the amended charts of the Japanese experts who visited India in February 1984. Only a small part of machinery, however was installed in the expected place, and wiring and plumbing work was not yet done.

(2) Measures to be Taken against Accidents of Damage and Loss to the Equipment and materials Provided

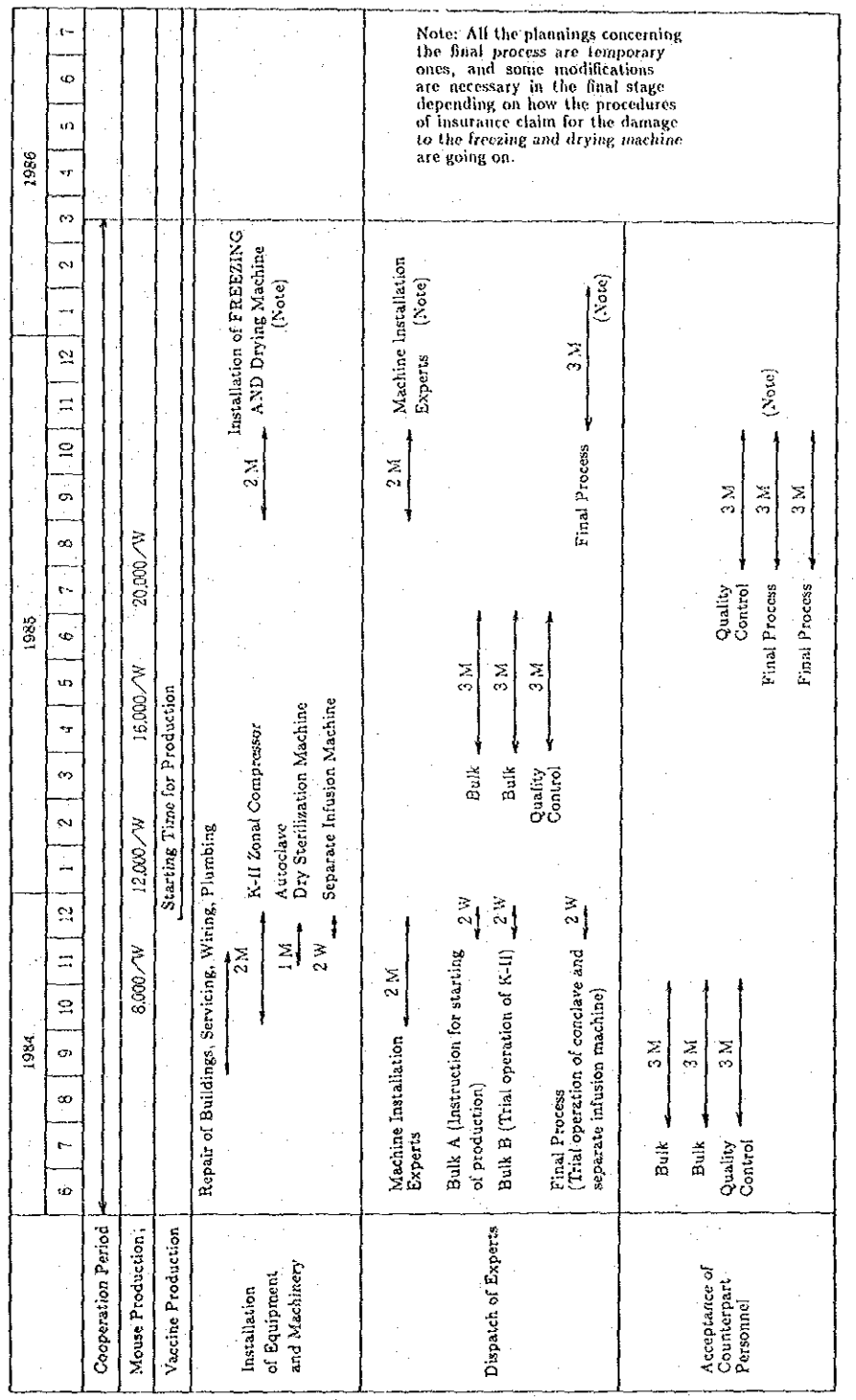
Machinery damage was confined chiefly to the freeze drying machine and the compressor pipe of the K-II Zonal Supercompressor. Damage to the former was especially serious, and the dispatched experts reported in February 1984, that it would cost nearly 100 million yen, the original cost of the machinery, and take better than one year to restore original functions.

This team predicted that the installation of the freeze drying machine, which was the most difficult problem, would be done in the autumn of 1985. It therefore decided to preserve the vaccine in its original liquid form, and make a new schedule for producing the bulk. But as it was evident that the Japanese Encephalitis Vaccine used in India must be a frozen and dried product, installation of the freeze drying machine at the earliest possible time was earnestly hoped for.

(3) Dispatch Planning of Japanese Engineers and Experts

It is essential to have participation and cooperation by Japanese engineers to install and operate such machines as a K-II Zonal Supercentrifuge, the autoclave, and the automatic filling machine. As mentioned before installation and start-up operation of these machines have been delayed for a long time for various reasons. The survey team feared that further delay would be a great obstacle to the accomplishment of this project and explained this fully to the Indian side, and made up the final planning schedule as shown in Table-2. Such work as repair of buildings, wiring, and the energy supply were half way done, and it was considered essential to have the closest contact possible with the respective groups concerned to carry out this plan faithfully.

Table-2 Amendment Plan for the Japanese Encephalitis Vaccine Production Project in India June 1984



3-3 Implementation Process after Amended Plan

3-3-1 Repair of Building and Installation of Machinery

Amended plans were made by the Mutual Consultation Team, and repair work on the JE Building was progressing smoothly so as to actually start the production procedures before making interim goods (bulk).

3-3-2 Starting of Production

As mentioned above, the installation of provided machinery was completed, and trial operation of the machinery was smoothly done, so the basis for producing the bulk was established. Toward the end of November in 1984, four experts, one expert for each of the bulk production and quality control procedures, and two experts for installation of machinery and trial operation were dispatched, and production of the vaccine started on December 3 that year.

3-3-3 Freeze Drying Machine for Producing Final Product

The amended plan was drafted, and bulk production procedures and quality control procedures for vaccine production went on smoothly, but the insurance claim for the damaged freeze drying machine did not.

With the amended plan completed, vaccine production was begun, virus floating fluid was produced, and operation of the K-II Zonal Ultracentrifuge became practical. The technique transference of bulk production procedures for interim products was almost completed. However, negotiations on the insurance claim were delayed a long time, as was delivery of the freeze drying machine to India. As such suspicion arose that the project would never be completed.

3-4 Evaluation Team

3-4-1 Dispatch of Evaluation Team

As described in "Implementation Process after Amended Plan", in the autumn of 1985 with the end of the cooperation term still several months away, it became obvious that production of the inactivated and dried vaccine impossible because of the freeze drying machine problem. The table of the first and amended plans, and the achievement record as of October 1985 is shown in Table-3.

Before dispatching the evaluation team, the committee inside Japan concluded that the project should not end at the scheduled time because no inactivated and dried vaccine had been produced. The committee arrived at the conclusion that it was desirable to extend the term until the final products were to be produced. Part of the Italian-made freeze drying machine would arrive in February 1986, and the Indian-made freeze drying machine would be delivered soon, and those machines would be used. The committee however, concluded that it wouldn't be desirable to extend the term until it became possible to produce two million closes of the vaccine and that it was reasonable to extend the term for one year only because a small amount of vaccine might be enough, if produced by the the Indian people. The evaluation team consisting of Dr. Fukai as its head and four other members was

dispatched in December 1985.

The chief aims of this survey team were summarized as follows:

1. Evaluation Data
   (1) Evaluation for appropriateness of input and output in each field (bulk, quality control, and final product)
   (2) Project management evaluation
   (3) Overall project evaluation
2. Measures to be taken for the future policy (draft)
   (1) Decision whether to extend the term or not
   (2) In case of an extension, develop plans and specific activities for the extended term.

3-4-2 Results of Evaluation Team

A. Engineering Branch
   (1) Buildings: Repair work to the inside of the JE Building had been nearly finished. As to the lift between the first and second floors, only construction of the outside walls was finished, and the rest of construction was to be finished in February 1986.

   As to the building for producing final products, partition work of the rooms (the dispenser room and the locker room), except for the freeze drying machine room was finished. Flooring and wall painting work was not yet finished as the duct work for ventilation had not been started.
   (2) Chief Equipment: All equipment provided by the Japanese side either through Grant aid Cooperation or technical cooperation was capable of good operation except the freeze drying machine and its accessories.
   Among the machinery expected to be provided by the Indian side, the autoclave and dry heating sterilizer were not yet delivered to JE Building.

B. Bulk Producing Branch
   (1) Productive Achievement
   The following is the productive achievements accomplished in respective stages as of December 13, 1985:

Partitioned pool (after K-II Zonal Centrifuge)	J85001-55005 (5 pools)	3,940 mℓ
Inactivation finished	30/85, 34/85-45/85	44.5ℓ
During inactivation	46/85-50/85	12.6ℓ

Table-3 Japanese Encephalitis Vaccine Production Project in India
Contrasted Chart of Planning and Achievement (from the Indian side)

These consisted of 56 batches of virus floating fluid (1/84-6/84, 1/85-50/85). The partitioned pool consists of 5 pools from J85001 to J85005, while the component virus floating fluid is listed on the table below.

Partitioned Pool No.	Virus Floating Fluid No.	Quantity of Floating Fluid	Quantity of Partitioned Pool (Statistical data omitted)
J85001	1/84 ~ 6/84 1/85 ~ 5/85	38,900 mℓ	900 mℓ
J85002	6/85 ~ 11/85	45,400 mℓ	940 mℓ
J85003	12/85 ~ 16/85	40,300 mℓ	700 mℓ
J85004	17/85 ~ 21/85	40,000 mℓ	700 mℓ
J85005	22/85 ~ 29/85 31/85 ~ 33/85	41,000 mℓ	700 mℓ

The total number of mice used for innoculation in one year from December 3, 1984 to December 7, 1985 was 195,497.

2. Conclusion

1) The important future problem in the bulk producing branch is to attain good quality in final production, and improvement of testing techniques was considered necessary for that. That the test is given outside the producing branch is important for assuring the objectivity of measurement value, but if close relations with each other should be lost, it would impede production. Especially, during the initial period, rapid feed-back is desired between production and its test, with the results of the test leading directly to the improvement of production. The nitrogen quantity measurement test was given outside the JE Project, and serious consideration was expected from the Indian side.
2) Due to a delay in mice production, the level of production was far below that aimed for in the beginning. It was thought essential at the test time to assure production of a vaccine which would pass the test even if the quantity was small. Once a product of perfect quality was obtained, great self-confidence would be acquired, and it would be possible to expect a great increase of production and productivity through their own efforts.

C. Quality Control Branch

From the investment aspect, although there was a delay in installation of facilities and machinery, by the autumn of 1984 installation was almost complete, everything was going well, and production began without any difficulty. From the production aspect, on the spot improvement on each item was made through minute instruction suited to the actual situation by the dispatched experts, and so the potency test, which is most important in the quality control, was given.

Even after the autumn of 1985 when the experts returned to Japan, improved experimental conditions were continued, and the potency test was repeated. From those facts, the quality of the personnel trained in Japan and the effectiveness of their training in Japan were proved, and that most of the technology transfer was thought to have been achieved, even though some problems regarding unfinished training in the test of protein content remained.

The improvement and investigation mentioned above was made when weather conditions were good, so there remained a sort of apprehension as to whether such good results could be obtained throughout a year, including the inclement weather of summer, and also whether a provision of good quality chicken eggs would be avalilabe for cell cultures of chicken embryos.

From the aspect of quantity, there were many misgivings and problems. The number of mice for innoculation in 1985 was 187,000, and that was less than a tenth the number of original planning (40,000/a week). When production increased, the quantity of work in the quality control branch would inevitably increase, and in that case, though there would be no problem in equipment, it was anticipated that problems would arise especially as to supply of articles for consumption. There would be a problem of supply on the Indian side as there were some types of machinery which were difficult to obtain in India, and as was pointed out in the report by experts, the shortage of cellulose penetrating membranes and millipore filters (6-2 cm in diameter) was mentioned by Dr. Rao Bhau, the chief in this branch, at the time of the survey. The shortage of consumption articles would become an unexpectedly big impediment to project implementation, and as in the case of an extension of the project term, it was to become an unexpected bottleneck. For the time being, the use of semi-reference vaccine was possible for training purpose in the potency test, but in the future, reference vaccine would be necessary in the potency test of the normal vaccine, so it was necessary to take its continuous supply into consideration.

D. Procedures for Producing Final Product (Separate Pouring and Freezing and Drying)

(1) Full-scale implementation of this procedure had been delayed for the reasons described below, and as such, it was considered impossible to complete this project within the scheduled term.

(a) Repair work on the damaged Italian freeze dryer (Model L-80) undecided due to a delay of its insurance claim

(b) Delay in delivery of the Indian freeze dryer (Model LV: 3200:20) as substitution

(c) Unfinished quality assay due to delay in establishment of quality control techniques for the bulk product

(2) Installation of the separate pouring line was completed, training for its use and maintenance completed, and trial use was finished, but the confirmation of the whole line (review of machinery in use, slight arrangement of machines, checking of sterilization) and general training were not yet finished.

(3) Repair of the damaged freeze dryer and installation of the freeze dryer for substitution was completed in February 1986 and repair work on a part of the building was under way. Therefore, the final procedure was thought to be possible only after the completion of said repair, installation, and modification work.

(4) When the mastery of techniques by the Indian side in various other procedures was considered, it was judged most proper to extend the project term for one year and to take proper measures to make completion of the project possible within the extended term. Considered to be a good method was to make visiting instructions together with the dispatch of experts, and the provision of spare parts and the visiting service was thought to be both effective and essential for the purpose of improving functions of previously provided machinery.

3-4-3 Project Soundness Appropriateness

This project was started in March 1982 with the aim of establishing a unit which could produce the Japanese Encephalitis Vaccine for two million people's use a year in four years. The facilities for direct production and quality control (chiefly for biological assay) that the Indian side provided had not ample space after construction, but assured necessary space. Equipment for production and quality control was provided through the grant aid funds and technical cooperation, which enabled them to produce the target amount of vaccine. Unfortunately, the equipment for producing the final product, the freeze dryer, was damaged on the way to the project site in September 1983. Negotiations between the insurance company and Indian officials concerning repair of the freeze dryer and exchange for a new one turned out to be more difficult than expected, so it became impossible to achieve the goal within the scheduled term.

In order to produce two million doses of vaccine again, 40,000 mice had to be supplied to the bulk branch a week, but capacity of mouse supply at the time of survey was only a tenth of the aim. Therefore, the amount of the stock of materials to produce the final product was far below the revised goal set up in June 1984.

Two factors, the unexpected damage to the freeze dryer and the unskilled dissemination of mice caused great delay in the initial planning. It was thought that if the two things mentioned above had proceeded smoothly, it would have been possible to accomplish the project within the projected period of time. Since those two accidents occurred on the Indian side, it was easy to lay all blame for delays on the Indian side. However, it must be admitted that the Japanese side had much blame for not understanding various conditions on the Indian side.

3-4-4 Extension of Project Term

This survey team made an investigation considering whether to extend the project term or not in accordance with the decision of the Committee inside Japan at the time of the dispatch of the Evaluation Team. The following was the description of the process to decide on the extension and activity plans during the extension term.

A. The fundamental thinking of the survey team when the problem of project extension was discussed with the Indian side under the direction of the Committee within Japan.

(1) As it is impossible to arrive at the stage of producing the final product during the initial term (by March 1986), it is necessary to extend the cooperation term to realize vaccine production.

(2) If the project should be ended without producing the final product, the investment made up to now would be lost.

(3) Therefore, extension of the term is thought to be unavoidable, but if the project is extended, the term should be limited to a minimum.

(4) In case of an extension of the term, rapid repair to the damaged freeze dryer cannot be expected, so that production of two million doses of vaccine now in the initial planning stage, is very difficult. It is advisable to set a realistic goal which can be achieved in a short time without relying on the present plan.

Based on the points mentioned above, the Team received the following results in discussion with the Indian side:

(1) The Indian side is also making strenuous efforts within the limited conditions, and a good deal of success has been achieved in technical transferrence.

(2) The Indian side earnestly desires the extension of the term to achieve the goal of the project, and expresses the willingness to make all efforts to accomplish the goal within the extension term, if the term should be extended.

(3) As the damaged freeze dryer, which had been the greatest obstacle, was expected to start operation in April 1986, there appeared the prospect of starting vaccine production in a comparatively short time. From the response mentioned above, it was judged acceptable to respond to India's wish by extending the cooperation term for a short period of time. The tentative plan for activities was drawn up as follows:

1) The extension term to be one year.

2) Production of the dry vaccine to be the aim achieved during the extension term, without insistence on the initial quantity of production (the initial aim being two million doses). Even if the quantity of produced vaccine was small, producing good vaccine was considered to be the achievement of the goal.

3-5 Implementation Process during Extension Term

3-5-1 Activity Plan and Procedures

Two Indian personnel were trained on final product procedures in Japan from January to March 1986 according to schedule, and returned to India after receiving training at the Microbe Pathology Research Institute of Osaka University, Kannonji Institute, and Denka Biology Research Institute. That meant that three Indian people got the same training, including the trainee who finished production training for the final product after coming to Japan in 1984.

In February 1986, parts of the damaged Italian freeze dryer were expected to be delivered from Italy, but it wasn't until March of that year that they actually were delivered. The installation of the parts and placement of the machine did not proceed as scheduled, so an Italian engineer visited India in July 1986, and gave instruction and supervision in the installation and placement of the parts, and at last, operation became possible. According to the initial planning, installation of the freeze dryer was to be finished in September 1983, and operation was to begin in October of that year, so it was two years and nine months behind schedule.

Upon receiving the report from India of the completion of repairs to the Italian freeze dryer, Japanese experts in final product procedures went to the site in September 1986, and provided detailed instruction during their two months' stay. In October of that year for a little over a month, two other Japanese quality control experts carried out instruction in quality control of the final product produced in India. The experts in production of the final product gave on the spot instructions and produced in total 7 lots of final product, and left them to be tested by quality control experts. When the production experts returned home in November that year, they brought back three lots of final product that had passed the test from among those that had gone trough the test, and asked the National Institute of Health for a further test.

3-5-2 Final Product Test in Japan

Among the three lots of the final product that the experts brought back on their return to Japan, they asked for the testing of two lots, Lot-1(I) and Lot-2(J) officially, and entrusted the National Institute of Health with the two lots of final product mentioned above with "the request form for test and inspection" attached to them. In the National Institute of Health, the official test was given as to whether or not "the Dry Japanese Encephalitis Vaccine" was suited for 'standard' of biological pharmacy, and both lots proved to be suited for the 'standard' in Japan.

3-5-3 Field Test Indian Final Product (Vaccine)

According to the activity program drawn up in December 1985 (Table-4), soon after final product testing in Japan, the test result of the final product was to be inspected with the Indian Evaluation Team in Japan and then a preliminary meeting for the implementation of the field test in India was to be held. All plans were postponed, due to the five month delay in repair to the Italian freeze dryer and it was in January 1987 that the result of the test given by the National Institute of Health was reported.

Further, due to office work delays on India's part, and as the schedule for the dispatch of the Indian Evaluation Team was not decided, the joint inspection meeting to be held in Japan in January 1987 had to be canceled. As the end of the one year's extension approached, it was decided that the result of the test was to be sent by letters to India, and that the field test using the final product was to be examined by the Indian team only.

In actuality, the field test was started in March 1987, when the last evaluation team from Japan visited India. The vaccination test was given to 42 employees, who had no counteractive antibody, at the Central Research Institute of Kasauli. The first day was called zero day, and on the seventh day the second vaccination was given, and on the thirty-fifth day, the second vaccination. Blood-gathering was done on the 35th and 42nd days after the first vaccination. The gathered blood was divided into two groups, and the value of counteractive antibodies was to be measured for each, one in India, and the other in Japan. Among the side effects surveyed after the vaccination, there were eight people who complained of pain among the forty-two people, and there was only one who complained of swelling on the vaccinated area.

The value of counteractive antibodies was tested on the serums of 42 vaccinated people, both 35 and 42 days after the vaccination at the National Institute of Health by using the Japanese Encephalitis Virus of the Nakayama-Institute of Health stocks and [826309 stocks] of India's freshly divided virus, and the result of the test is shown in Tables 13-A&B. As shown in the table, the counteractive antibody against the Nakayama-National Institute stock virus shows a rising antibody value in all the vaccinated people, and after the third vaccination, further rise in the value of the antibody. Against [826309 stocks] of India's freshly divide virus stocks, 81 percent of the vaccinated people proved to have high antibodies after two vaccinations, and after the third vaccination all the vaccinated people proved to have high counteractive antibodies, thus proving the excellence of the Japanese Encephalitis Vaccine.

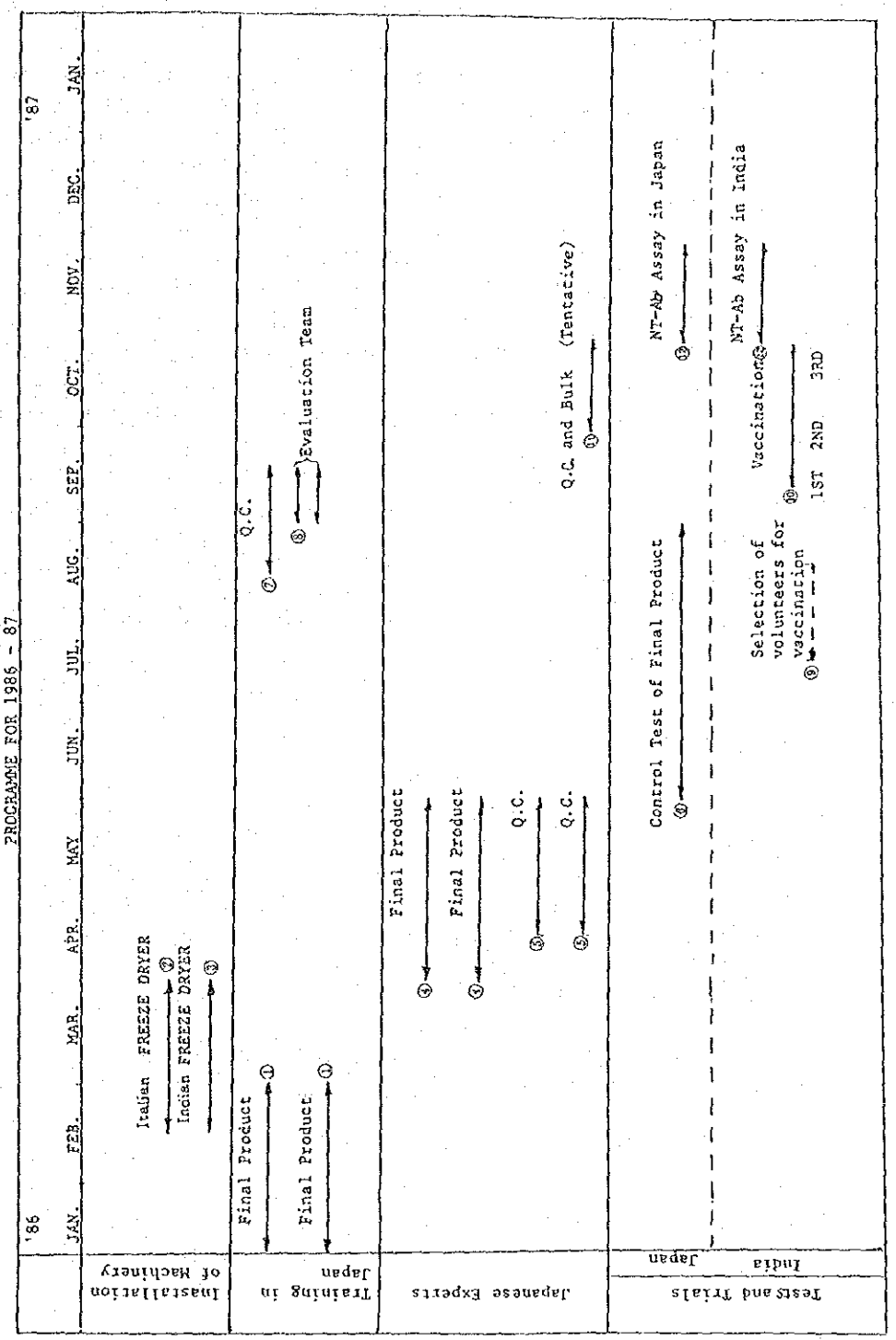
3-5-4 Dispatch of Final Evaluation Team after One Year Extension

The last evaluation survey team consisting of 6 members headed by Dr. Oya, visited India in March 1987, and evaluated implementation conditions of this project and its achievement of the goal. The summary was as follows:

(1) Training of thirteen personnel in Japan was carried out as scheduled in three branches, bulk production, production of the final product, and quality control. Experts were dispatched on the short-term basis as a result of consideration not to cause inconveniences to the work in respective agencies, so the dispatch was carried out effectively. The total number of dispatched experts was thirty. Accordingly, it was judged that the aim of dispatch planning on this project was almost achieved.

(2) The large-sized freeze dryer provided by the Grant Aid Cooperation was damaged in the transport accident in India. As that machine was insured against casuality the repair work restored it to normal operational capacity at the expense of the insurance company. As proven by the quality of the final product, its functions are presently satisfactory.

Table 4 Programme for 1986-7



(3) Since the implementation of this project was delayed in the accident mentioned above, the cooperation term was extended for one year.

(4) In the final fiscal year of the cooperative term, seven lots of the final vaccine product were produced.
Among them two lots were inspected at the Japanese National Institute of Health, assuring that its quality satisfied the Japanese inspection standard fully. This fact is rated highly as proof that technology transfer as regards the project was completely achieved. Especially, it is worth noting that the vaccine passed in the protein content test very easily in view of the fact that the "biological pharmacy standard" of this test was most difficult to pass.

(5) The initial aim of producing two million doses of vaccine a year could not be achieved by the termination of the cooperative term. The reasons were the shortage of produced mice, materials for vaccine, and in addition the delay of the project due to the delay in installation of major equipment. From the data reported on the Indian side, the goal will be achieved within two years by consolidating the mice dissemination plan to assure the necessary number of mice.
It is India's problem to establish a system of mass production of mice to meet the needs of the Indian people, and it will not be an obstacle to accomplishment of the present project.

(6) Although after the project has ended, there are problems to be solved by the Indian side to realize practical use of the vaccine; for example, the clinical test of the Japanese Encephalitis Vaccine produced in India, and a quality maintenance assurance period for the vaccine. As for the clinical test, as already explained in '3-5-3', the field test was started on 42 healthy adults in March 1987, and in June of that year, the scale of the plan was expanded and a field test for 5,000 people was planned.

(7) Another problem is the change of quality over time. When the level of humidity of the vaccine in the experimental stage was measured at regular intervals in Japan, it tended to rise slightly. According to the "Biological Pharmacy Standard" criteria in Japan, the effective period of the Japanese Encephalitis Vaccine is five years, but in the case of the Indian made Japanese Encephalitis Vaccine, the effective period should be determined independently based upon the result of the quality change test over time.

(8) As a problem to be solved in the future, the Indian side requested continuous double checking of the antibody in the field test, and the provision of reference vaccine. To accomplish this, it is desirable that the Japanese side give the greatest cooperation possible.

4. ACHIEVEMENT AND EVALUATION OF THE PROJECT

4-1 Achievement Level of This Project

The initial goal of this project was to produce two million doses of the dry Japanese Encephalitis Vaccine (National Institute-Nakayama stocks). Total quantity of the produced vaccine at the end of the project was 100 thousand doses of final product, 5 percent of the initial aim in quantity. When the final evaluation was conducted, the plan that the Indian side proposed was for one million doses in 1988, and two million in 1989.

4-2 Summary of Evaluation

4-2-1 Making Plans

The initial plan drawn up when the Record of Discussions was signed took into consideration about one year in reserve. In Japan, experience and knowledge about Japanese Encephalitis Vaccine production had been accumulating for the past 25 years, so the plan was drawn up on he basis of that experience and knowledge. And due to the efforts of the Japanese experts who worked at the project site and various organizations that carried out the training of the Indian personnel in Japan, and due to the achievement of the personnel trained in Japan, there were few gaps to hinder implementation of the project.

The initial plan setback was caused by the damage of the chief machinery in an accident. The accident occurred due to a lack of fundamental knowledge on transport and conveyance of weight cargo. This lack of thorough training quite regrettable. In addition, the Indian side took much time in taking necessary measures after the accident occurred. As the accident occurred in India, and as the Government of India carried casualty insurance for the machinery, the damage claim was India's problem, and the Japanese side was not allowed to meddle in their negotiation. Finally, an amendment plan was drawn up between the Implementation Survey Team and the Indian side, and planning the process accelerated at last. It cannot be denied that the twice a month reports of how preparatory work was proceeding from the Indian side helped the progress of the plan. The amended plan had a strong influence on the insurance claims for damaged machinery and repair, though this problem was not included in the amended plan.

Due to these problems, the initial implementation plan and the modified plan were not implementable, although now all is proper.

As the Indian side could not foresee when the damaged freeze dryer for the final product could be repaired, they hesitated to go on with the plan of mice dissemination, and more importantly Japan neglected instruction concerning mice dissemination techniques, and as such they could not carry on the mice production plan smoothly. The last evaluation team offered to study this as a follow-up problem, if necessary.

4-2-2 Project Operation and Administration

In the implementation stage of this project, three pillars of technical cooperation – machinery provision, dispatch of Japanese experts, and Indian counterpart training in Japan – went on smoothly, so technology transfer was carried out smoothly.

If a defect in the project implementation were to be pointed out, it might be that the long-term expert as team leader was not dispatched. Because of that, information on the implementation of the project depended upon communication contact from the Indian side, and detailed information depended upon contact with the Japanese experts or their report upon return to Japan. Most of the project developments were made known as described above, and there were no big obstacles, but had there been an expert who took on the business of negotiating for the insurance claims on the damaged machine, it would have helped. The Chief of the Central Research Institute in direct charge of this project on the Indian side was not given adequate power to make decisions and there were lots of things needing the approval of authorities in the Ministry of Health and Welfare, and there were lost opportunities because it unexpectedly took such a long time to get official decisions. Such things ought to have been recognized beforehand. It is regrettable that there was a shortage of information about the state of affairs in India and the Indian people.

APPENDICES

1. The Record of Discussions (R/D)

The Record of Discussions between the Japanese Implementation Survey Team and the Authorities Concerned of the Government of the Republic of India on the Japanese Technical Cooperation for the Japanese Encephalitis Vaccine Production Project

The Japanese Implementation Survey Team (hereinafter referred to as "the Team") organized by the Japan International cooperation Agency (hereinafter referred to as JICA) and headed by Dr. Akira Oya, Director, Department of Virology and Rickettsiology, National Institute of Health, Ministry of Health and Welfare, visited the Republic of India from March 2, 1982 to March 13, 1982 for the purpose of working out the details of the technical cooperation programme concerning the Japanese Encephalitis Vaccine Production Project in the Republic of India.

During its stay in the Republic of India, the Team exchanged views and had a series of discussions with the Indian authorities concerned in respect of the desirable measures to be taken by both Governments for the successful implementation of the above-mentioned Project.

As a result of the discussions, the Team and the Indian authorities concerned agreed to recommend to their respective Governments the matters referred to in the document attached hereto.

New Delhi, March 12, 1982

Dr. Akira Oya
Head of Japanese
Implementation Survey Team

Dr. I.D. Bajaj
Director General of Health Services
Ministry of Health and Family Welfare

in the presence of

(B.M. Oza)
Joint Secretary
Ministry of Finance

THE ATTACHED DOCUMENTS

I. COOPERATION BETWEEN BOTH GOVERNMENTS

1. The Government of Japan and the Government of the Republic of India will cooperate with each other in implementing the Japanese Encephalitis Vaccine Production Project (hereinafter referred to as "the Project") for the purpose to establish and develop the technology of the Japanese encephalitis vaccine production and thus to contribute to the control of Japanese encephalitis (hereinafter referred to as "JE") and improvement of public health in the Republic of India.
2. The Project will be implemented in accordance with the Master Plan which is given in Annex I.

II. DISPATCH OF JAPANESE EXPERTS

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to provide at its own expense services of the Japanese experts as listed in Annex II through the normal procedures under the Colombo Plan Technical Cooperation Scheme.
2. The Japanese experts referred to in 1 above and their families will be granted in the Republic of India the privileges, exemptions and benefits no less favourable than those accorded to experts of third countries working in the Republic of India under the Colombo Plan Technical Cooperation Scheme.

III. PROVISION OF MACHINERY AND EQUIPMENT

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to provide at its own expense such machinery, equipment and other materials necessary for the implementation of the Project as listed in Annex III, through the normal procedures under the Colombo Plan Technical Cooperation Scheme.
2. The Articles referred to in 1 above will become the property of the Government of the Republic of India upon being delivered c.i.f. to the Indian authorities concerned at the ports and/or airports of disembarkation, and will be utilized exclusively for the implementation of the Project in consultation with the Japanese experts referred to in Annex II.

IV. PROVISION OF STRAIN AND REFERRENCE VACCINE

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to provide at its own expense the strain and the referrence vaccine necessary for the JE vaccine production through the normal procedures under the Colombo Plan Technical Cooperation Scheme.
2. The strain and the referrence vaccine will be utilized exclusively for the Project in consultation with the Japanese experts referred to in Annex II.

V. TRAINING OF INDIAN PERSONNEL IN JAPAN

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to receive at its own expense the Indian personnel connected with the Project for technical training in Japan through the normal procedures under the Colombo Plan Technical Cooperation Scheme.
2. The Government of the Republic of India will take necessary measures to ensure that the knowledge and experience acquired by the Indian personnel from technical training in Japan will be utilized effectively for the implementation of the Project.

VI. SERVICES OF INDIAN COUNTERPART AND OTHER PERSONNEL

1. In accordance with the laws and regulation in force in the Republic of India, the Government of the Republic of India will take necessary measures to secure at its own expense necessary services of Indian counterpart personnel as listed in Annex IV and other personnel as considered necessary.
2. As to the Indian counterpart personnel, the Government of the Republic of India will endeavour to allocate the necessary number of suitably qualified personnel corresponding to each Japanese expert to be dispatched by the Government of Japan as specified in Annex II, for effective and successful implementation of the Project.

VII. MEASURES TO BE TAKEN BY THE GOVERNMENT OF THE REPUBLIC OF INDIA

1. In accordance with the laws and regulations in force in the Republic of India, the Government of the Republic of India will take necessary measures to provide at its own expense:
   (1) Land, building and facilities as listed in Annex V;
   (2) Supply or replacement of machinery, equipment, instrument, vehicles, tools, spare parts and any other materials necessary for the implementation of the Project other than those provided through JICA under III above;
   (3) Transportation facilities and travel allowance for the Japanese exerts for the official travel within the Republic of India;
   (4) Suitably furnished accommodations for the Japanese experts and their families;
   (5) Medical facilities for the Japanese experts and their families.
2. In accordance with the laws and regulations in force in the Republic of India, the Government of the Republic of India will take necessary measures to meet:
   (1) Expenses necessary for the transportation within the Republic of India of the articles referred to in III above as well as for the installation, operation and maintenance thereof;
   (2) Customs duties, internal taxes and any other charges, if any, imposed in the Republic of India on the articles referred to in III above;
   (3) All running expenses necessary for the implementation of the project.
3. The Government of the Republic of India shall take necessary measures to guarantee that technical know-how of the JE vaccine production shall not be transferred to third person and third country except to other Indian Government Institutions with previous approval by the Japanese authorities. The vaccine produced will be used only in India, except Governmental donation in cases of epidemic emergency situations. In such cases, it shall be subjected to previous approval by the Japanese authorities.

VIII. ADMINISTRATION OF THE PROJECT

1. The Director General of Health Services in the Ministry of Health and Family Welfare, the Government of the Republic of India, will bear the overall responsibility for the implementation of the Project.
2. The Director of the Central Research Institute in Kasauli (hereinafter referred to as "the Director of CRI") will be responsible for the administration and operation of the Project.
3. For the successful implementation of the Project, a coordinating committee will be established with the members as listed in Annex VI.
   The committee will regularly meet once a year.
   The functions of the Committee are as follows:
   (1) To formulate the detailed annual working plan of the Project
   (2) To review the implementation of the Project.

4. A meeting to deal with the technical matters, under the chairmanship of the Director of CRI, will be held monthly with the members of the Indian counterparts and the Japanese experts.
5. The Japanese experts will give the necessary technical guidance and advice related to the matters pertaining to the implementation of the Project.

IX. CLAIMS AGAINST JAPANESE EXPERTS

The Government of the Republic of India undertakes to bear claims, if any arises, against the Japanese experts engaged in the Project resulting from, occuring in the course of, or otherwise connected with the discharge of their official functions in the Republic of India except for those arising from the willfull misconduct or gross negligence of the Japanese experts.

X. MUTUAL CONSULTATION

There will be mutual consultation between the two Government on any major issues arising from or in connection with this Attached Document.

XI. TEAM OF COOPERATION

The duration of the technical cooperation for the Project under this Attached Document will be four(4) years from March 12, 1982.

ANNEX I MASTER PLAN

1. Objective

   The Project aims at contributing to the improvement of the availability of the JE vaccine in Indian through establishment and development of technical know-how on the JE vaccine production.

2. Implementation

   The Central Research Institute in Kasauli has responsibility for the JE vaccine production and its quality control with the guidance of the Coordinating Committee.

   A tentative implementation schedule of the Project is shown in Table I.

3. Method of JE vaccine production and control

   (1) Source materials

   The stain Nakayama NTH of virus and healthy mice of 3 - 5 weeks of age shall be used.

   (2) Process

   The brains of the mice inoculated intracerebrally with the virus strain for production shall be harvested before death with showing typical signs of encephalitis.

   The harvested brains shall be triturated in phosphate - buffered saline and centrifuged. The supernatant shall be collected, and treated by protamine sulfate to serve as the virus suspension.

   After that, formaline shall be used for inactivation of virus and the virus antigen shall be purified by the method of sucrose gradient centrifugation using Zonal K-II ultracentrifuge.

   The resulted suspension shall be subjected to the tests.

   The bulk materials shall be made by collecting above suspensions. The bulk materials shall be diluted in suitable medium to serve as the final bulk.

   The final bulk shall be subjected to the tests.

   The above final bulk shall be dispensed into the small vials and freeze-dried to serve as the final products.

   The final product shall be subjected to the tests.

   The vaccine shall be applied to human after completment of the required assay procedures.

4. Activities

   Animal breeding ..... Mouse breeding necessary for the vaccine production

   Bulk process ..... Establishment of the bulk process technology of unit and its development

   Final product process ..... Establishment of the final product process technology of unit and its development

   Quality control ..... Establishment of the assay technology for validity and safety of vaccine

   Maintenance of equipment ..... Establishment of operational and maintenance technology for the equipment

ANNEX II JAPANESE EXPERTS

Experts in

1. Virology on bulk process
2. Engineering/virology on final product process
3. Virology and biochemistry on quality control
4. Other fields mutually agreed upon as necessary

Note: One of the Japanese experts will be nominated as Team Leader.

ANNEX III LIST OF THE ARTICLES

1. Equipment for bulk process, final product process and quality control.
2. Materials and reagents for bulk process, final product process and quality control.
3. Laboratory measuring instruments
4. Glasswares
5. Vehicles
6. Copy machines
7. Other machinery, equipment and materials mutually agreed upon as necessary.

ANNEX IV LIST OF INDIAN STAFF

1. Management ..... Project manager
2. Mouse breeding ..... Verterianarian
3. Bulk process ..... Virologist
   Virological/Mechanical technicians
4. Final product process ..... Engineer
   Virologist
   Mechanical technicians
5. Quality control ..... Virologist
   Biochemist
6. Other personnel required for the implementation of the Project as mutually agreed upon.

ANNEX V LIST OF LAND, BUILDING AND FACILITIES

1. General ..... Facilities for supply of electricity, water, steam, gas, etc.
2. Mouse breeding ..... Breeding room, facility of fan heater
3. Bulk process ..... Lifting facility, boiler
   Ante room, inoculation room, housing for infected mice, harvesting room, decontamination room, refrigerated contrifuge room, purification room, homogenization room, cold room, dress changing room, recording room, store room, office

4. Final product process ..... Boiler
   Ante room, washing room, preparation room, stock room, filling and sealing room, freezdrying room, preparation room for final bulk, dress changing room, hand washing room, locker room, recording room, office
5. Quality control ..... Lifting facility
   Housing for infected animals, housing for non-treated animals, Tissue culture room, sterility test room, virus room, testing room, incubator room, preparation room, decontamination room, store room, office
6. Other as mutually agreed upon

ANNEX VI COMPOSITION OF THE COORDINATING COMMITTEE

Chairman: Additional Secretary of Health, Ministry of Health and Family Welfare (MHFW), Government of India

1. <Indian Side> The director General of Health Services (MHFW) of his representative
   <Japanese Side> Experts
2. <Indian Side> Representative of the Drug Controller of India
   <Japanese Side> Members of Japanese Mission dispatched by JICA
3. <Indian Side> Representative of National Institute of Virology in Pune
   <Japanese Side> Representative of JICA New Delhi Office
4. Representative of Central Research Institute in Kasauli
5. Representative of Department of Economic Affairs, Ministry of Finance
6. Other officials appointed by the chairman
   Note: Officials of the Embassy of Japan may attend the Coordinating Committee as observers.

2. List of Main Machinery and Equipment Granted

1982	Colorimeter (Hitachi 330)	¥5,800,000
	Temperature Recording Machine (Mitamura EH200-12)	¥1,000,000
	CO_2 Incubator (Ikemoto 102-B-2)	¥2,800,000
	CO_2 Incubator (Ikemoto 1002-A-2)	¥1,590,000
	Laminar Flow Cabinet (Hitachi 1302-EC)	¥2,050,000
1984	Small-sized Cooling Centrifuge (Hitachi 05PR-22)	¥1,240,000
	K-II Zonal Ultracentrifuge (Columbia Trade)	¥6,720,000
1985	Chemical Balance	¥1,520,000
1986	Ethylene Gas Strilizer (Tokkyo Rika Kogyo)	¥4,610,000

JICA