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18419

Distr.
RESTRICTED

IO/R.153
7 June 1990

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

ORIGINAL: ENGLISH

MANUFACTURING TECHNOLOGY OF YAG-LASER FOR MEDICAL EQUIPMENT

DG/CPR/88/070

PEOPLE'S REPUBLIC OF CHINA

Technical report: Project formulation mission*

Prepared for the Government of the People's Republic of China
by the United Nations Industrial Development Orgarization

Based on the work of Mr. L. N. Soms,
consultant in YAG lasers for medicine

Backstopping officer: Mr. M. Boutoussov
Institutional Infrastructure Branch

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* This document has not been edite .

EXPLANATORY NOTES

The UNDP official rate for February 1990 is
US$ 100= FEC 471.03

CICETE	China International Centre for Economic and Technical Exchange
CW	current wave
FEC	Foreign Exchange Certificate of People Republic of China
LMI	laser medical instrument
MMEI	Ministry of Machinery and Electronics Industries
NCRIEO	North China Research Institute of Electrooptics
PAC	Project Advisory Council
PFF	Project Formulation Framework
PFM	Project Formulation Mission
PRC	People Republic of China
R&D	research and development
YAG	Yttrium-Aluminum Garnet (type of laser crystal)
Prodoc	project document

ABSTRACT

This report describes work performed by UNIDO consultant Dr. Soms from 09.02.90 to 01.03.90 during the Project Formulation Mission connected with the project `Manufacturing Technology of YAG Lasers for Medical Equipment`, CPR/89/005.

The mission objectives were {i} to get acquaintance with the technical conditions, abilities and needs of NCRIEO connected with the project implementation, {ii} to precise the technical approaches and contents of the project, and {iii} to prepare, with consultations with the representatives of CICETE, MMEI, NCRIEO, and staff members of UNDP and UNIDO, the Prodoc which meets UNDP standards. At the beginning of mission the Prodoc draft was prepared by NCRIEO.

The extensive discussions concerned items {i-iii} were obtained with NCRIEO representatives.These discussions havedetermined more precisely the contents of the activities and outputs during the project implementation and the technical problems to be solved. The elaborated decisions and conclusions were taken into account during the final Prodoc draft preparation.

The approach taken has been that of developing during the project implementation {i} the technologies of three basic laser elements {namely, pumping lamps, laser crystal rods and optical coatings}, and simultaneously {ii} the design and manufacturing technologies of lasers and laser-based medical instruments. On the first stage of project implementation, when corresponding elements technologies are not yet developed and country-made laser basic elements are not available, the prototypes of medical lasers should be manufactured using imported laser elements, similar to those, which technologies are implemented. These laser prototypes {i} will be the reference points providing quantitative check-up of country-made laser elements, and {ii} will allow the medical personnel in China to develop up-to-date methods of laser surgery, providing necessary feed-back to improve and to precise technical specifications of medical lasers and instruments before the beginning of mass production and commercialization process.

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1.INTRODUCTION

This report is written by UNIDO consultant Dr. Leonid Soms and describes his work performed from 09.02.90 to 01.03.90 during the Project Formulation Mission for the project CPR/89/005.

Taking into account the importance of advanced technologies implementation in the human-oriented branches of national industry, the Chinese Government has planned the development of laser-based medical instruments as part of the efforts of industrial modernisation. Because of lack of qualified technical personnel and many of required technologies in such fields as lasers and LMI`s, the Government of China and UNDP agreed to prepare the project entitled `Manufacturing Technology of YAG Lasers for Medical Equipment` {CPR/89/005}.

The Project Formulation Framework was prepared by NCRIEO in December 1988 and was under clearance in UNIDO and UNDP during 1989. Preliminary comments on the PFF were made and issued on April 1989. The essentials of these comments are reduced to (i) approval of main technical ideas of PFF, namely, the selection of solid-state Nd:YAG laser as basic for LMI development and further manufacturing,and of the identification of some key components of development. At the same time it was underlined (ii) the necessity of the system approach to the development of technologies connected to such highly competitive area as LMI`s, and so (iii) the necessity of thorough preparation of the Prodoc. The recruitment and Goverment of China approval of UNIDO consultant for project formulation mission was completed to December 1989.

The UNIDO consultant in solid-state lasers manufacturing for medical purposes (laser surgery) (job description see Annex 1) was sent to Beijing (i) to discuss the PFF, prepared by NCRIEO; (ii) to get acquaintance with the technical and technological conditions, abilities and needs of NCRIEO, connected with the project implementation; (iii) to define and precise the technical approach and the contents of project activities; and (iiii) to prepare, with consultations with the representatives of NCRIEO, CICETE, MMEI and UNIDO and UNDP, the complete Prodoc that meets

requirements of UNDP standards and incorporates suggestions outlined during the discussions.

After the briefing in UNIDO residence (Vienna, Austria, 20.02.90 - 08.02.90) UNIDO consultant Dr. Leonid Soms arrived in Beijing on February 09 and departed March 01. At the beginning of PFM the Prodoc draft was prepared by NCRIEO.

Extensive discussions and redrafting of Prodoc were undertaken (meetings schedule see Annex 2), so at the beginning of the mission of UNIDO Backstopping officer (February 21) [a] redrafted version of Prodoc was prepared. During subsequent discussions the technical backgrounds of Prodoc remained and the optimal implementation modalities were under thorough scope. According to the opinion of UNIDO representatives the governmental execution of the project would not allow it's optimal implementation from the viewpoints of the bidding/subcontracting, the training activities, and supporting activity, the last being obviously necessary for the project dealing with such high-tech area as laser medicine. On the contrary, the UNIDO execution of the project (or at least of its main parts) could provide the quality improvement of the project implementation due to the developed UNIDO managerial international infrastructure that becomes available for the project.

This point of view was expressed and discussed both with the CICETE and NCRIEO, from one side, and UNDP, from the other.

The CICETE propositions for UNIDO participation were expressed as activities in training and consultant programs, and in the organizing the work on laser and LMI prototyping.

The propositions to extend the output of the project connected with the medical laser instruments design and manufacturing were put during preparatory technical meetings with UNDP that preceded PAC meeting (the PAC meeting was not held at the departure of Dr. Soms.) The corresponding corrections to the Prodoc are prepared by UNIDO representatives.

2.MISSION ACTIVITIES

A.Findings.

The sequence of mission activities described below corresponds the listed in the Introdution (page 5) mission objectives.

Prodoc draft analysis.

The Prodoc draft prepared by NCRIEO was available upon the arrival. The contents of Prodoc was similar in its main features to the PFF, with a strong emphasis to the laser elements technologies development and with unsatisfactory (upon UNIDO expert opinion) activities connected with the laser and laser medical instruments design, manufacturing and prototyping.

Technical situation in NCRIEO.

The acquaintance with the technical conditions, abilities and needs of NCRIEO connected with the project, as well as with the institute`s experience in medical lasers development and manufacturing has shown the next:

1) General impression.

The institute was founded in 1956. Nowadays the total number of staff is approximately 1500. The institute is subordinate to the Ministry of Machinery and Electronics Industries, Division of Optical Electronics and Semiconductors. Main fields of activities: infrared techniques and solid-state lasers R&D and applications.

The number of staff engaged with the laser activities is approximately 150-200. Fields of applications: lasers for technological applications; lasers for medical applications; lasers for the rangefinders.

The infrastructure of NCRIEO contains all required technological lines that are necessary to develop, design and manufacture solid-state lasers (including laser crystal growth, optical elements developing, pumping lamps production, mechanical and hydraulic components design and manufacturing, power supplies

control and electronic monitoring system production.

The institute is engage in such R&D activities in quantum electronics technologies as new solid-state laser active media and nonlinear crystals growth, ultra-short pulses generation etc. The institute edits its technical journal where the original articles are published.

Many of scientific staff are speaking fluent English.

The institute is situated in the North-East part of Beijing and occupies some (about 5-7) 3-5-stored buildings erected in 50`s - beginning of 60`s. The part of them (not connected with discussed project) has been recently renovated, so the institute has experience in modernisation activity.

2) Medical lasers and instruments production in NCRIEO.

During last 5 years NCRIEO has developed and manufactured approximately 100 lasers for surgery (model JY-C, multimode CW YAG-Nd lasers, output power up to 100 W, with fiberoptics output) and some tens lasers for ophthalmology (model JYZ-1, Q-switched YAG-Nd, TEM-00 mode, 40 mJ per pulse). These lasers are distributed between many leading hospitals in PRC, and more then 20.000 operations were made using these lasers. NCRIEO provides post-sell service of manufactured equipment. During these years the accumulated experience has shown the necessity of the radical improvements and modernisation of all main technologies.

3) Basic laser elements technologies.

(i) Pumping lamps.

The molybdenum-foil technology for the electrical connection with the lamp electrodes is still used since the beginning of 1960`s. The technology is complicated, does not provides the possibility of automatization, leads to the irregular shape of the lamps. The used quartz tubes are of bad optical quality, there are many scratches and sometimes impurities, which can lead to the decrease of its lifetime. As for now the lifetime of the CW Krypton lamps is approximately 100 hours under the loading of 280 W/square cm (electrical power per unit of inner wall tube surface), that is approximately 4 times worse then modern level.

NCRIEO has contacts with EG&E Electrooptics (USA) as possible subcontractor.

(ii) Crystal growth.

Institute has 4 Czochralsky crystal growth apparatus of China origin with temperature control (no automatic weighing control). Available crystal size; boules Ø(25-50)x(150-200)mm, laser rods up to Ø(8-10)x(100-120)mm; dopant concentrations up to 0.9% at.; optical quality satisfactory (appr. 2 fringes across Ø9 mm), for the best crystals no visible small-scale optical inhomogeneities; transmittance between two crossed polarizers appr. 2-5%.

Testing performed in the institute includes:

-interferometric fringes measuring;

-residual birefringence;

-scattering of He-Ne laser beam measured through the side surface;

-laser efficiency under CW and free-running oscillation pulse operation as compared with some etalon elements (maximal achieved efficiency is about 3,5%, typically lower, appr. 2%)

NCRIEO has contacts with Airtron Laser Electrooptics Group (Litton Systems, USA) as the possible subcontractor.

(iii) Optical elements development (grinding and polishing).

The department has about 30 workers in the workshop. No special technologies for grinding and polishing of the optical surfaces for the high intensive laser light operation. No reliable technologies for polishing materials preparation, so the particles of the different size are presented in the polishing materials and produce the scratches on the polished surfaces.

(iv) Optical coatings.

Non-automated coating equipment with old-fashioned oil diffuse-pumps. Electron-beam evaporation of TiO2, ZrO2, SiO2. Maximal achieved reflection coefficient us about 99,8%.Cleaning of substrates with KCrO4 - H2O solutions in a clean housing with laminar air flow, but no air-conditioning and anti-dust facilities in the laboratory. Laser threshold damage density of the coatings on the glass substrates is ~4-5-J/sq.cm at the pulse duration of ~10 ns, that is about 5 times worse then modern level.

NCRIEO has contacts with Leybold AG (FRG) as possible subcontractor.

(v) Laser design and manufacturing.

The following notes are related to CW laser for surgery; the pulse ophthalmological laser in the disassembly was not available to look at.

-Pumping cavity: the laser rod and lamp are inserted in quartz tubes (for lamp - quartz is doped with Cerium in order to filtering UV part of radiation) and are cooled with the deionized distilled water. Elliptical pump reflector (air-contacted silver coating on the polished brass). The rod ends are sealed in brass tubes with polymerized glue.

Pumping cavity design has some intrinsic defects: (a) the possible bad cooling of lamp that can lead to its damage and even explosion; (b) the impossibility of assured cleaning of rod surfaces; (c) the relatively low pump cavity efficiency.

-Laser cavity: the switch-on of the laser beam is made by intracavity electromechanically controlled screen; the reliability of this screen needs to be improved.

-Power supply: according to the declaration of NCRIEO representatives, the power supply scheme must be redesigned in order to improve the reliability, efficiency and weight/volume ratio.

-Fiberoptic ccupling.

The simplest and not reliable design of laser output - optical fiber coupling is used (focusing lens and adjustable fiber end) The possible misalignement of focused high power laser light leads to melting of plastic fiber envelope.

The up-to-date ideas for contact surgery using cooled sapphire tips are under discussions and preliminary investigations.

Project contents discussions and Prodoc redrafting.

The described above technical situation and its correlation with the Prodoc draft were thoroughly discussed with NCRIEO representatives, and the outputs, activities and inputs distribution of the project were revised. The common opinion about the project technical contents was achieved (see Annex 3, Joint Technical Minutes)

According the revised technical contents of the project, the necessary corrections were performed, and the redrafted Prodoc was prepared. The essentials of these corrections are in the enlargement of the activities concerning lasers and LMI prototypes designing and manufacturing technologies.

B.Recommendations.

1. The optimal way of development of the laser surgery and ophthalmology in PRC consists in the implementation of the project 'Manufacturing Technology of the YAG Lasers for Medical Equipment'. The implementation of the project should be done by North China Research Institute of Electrooptics (Beijing). This institute has all necessary technical conditions for the project implementation and has accumulated some own experience in laser surgery and ophthalmology instruments prototyping and manufacturing.

2.The outputs of the project (i.e. developing of the technologies for the basic solid-state laser elements: lamps, laser crystals, rods and optical coatings, according with the design technology of laser and laser medical instruments and manufacturing of prototypes of two types of these instruments: for laser surgery and ophthalmology) correspond to the main goal of the project and to the existing status of technologies in NCRIEO. The special attention should be payed to the activities connected with laser medical instruments prototyping, taking into account the importance of the the development,manufacturing and demonstration of up-to-date equipment apt to further commercialization process.

3.The optimal mode of the project implementation is the participation of UNIDO as the executing agency. The large experience in the management of the complex international projects, including projects in the high-tech areas, as well as the developed infrastructure to provide effective subcontracting, bidding and training and the possibilities for the supporting activities would be for the great benefit to the project.

ANNEX 1

JOB DESCRIPTION

CONSULTANT IN SOLID-STATE (ND-YAG) LASER MANUFACTURING FOR MEDICAL PURPOSES (LASER SURGERY).

THE CONSULTANT WILL BE ASSIGNED TO THE NORTH CHINA RESEARCH INSTITUTE OF ELECTROOPTICS (NCRIEO). WORKING IN CLOSE CO-OPERATION WITH THE SPECIALISTS AND AUTHORITIES OF NCRIEO. HE WILL PARTICULARLY BE EXPECTED TO:

1. PROVIDE AN ASSESSMENT OF THE STATUS OF THE TECHNOLOGY USED BY NCRIEO FOR MANUFACTURING OF THE KR-LAMPS USED FOR OPTICAL PUMPING OF SOLID-STATE LASERS.
2. PROVIDE AN EVALUATION OF THE TECHNOLOGY POSSESSED BY NCRIEO FOR MANUFACTURING OF ND-DOPED YAG CRYSTALS FOR LASERS AND QUALITY KONTROL METHODS USED TO CHECK SAMPLES.
3. PROVIDE A SURVEY OF VACUUM-COATING TECHNOLOGY USED BY NCRIED TO DEPOSIT ANTIREFLECTING AND REFLECTION LAYERS ONTO MIRRORS, WINDOWS AND CRYSTAL SURFACES.
4. ADVISE UPON THE OPTIMAL WAYS TO UPGRADE THE TECHNOLOGIES ENUMERATED IN 1-3 IN ORDER TO SECURE THE RELIABLE OPERATIONAL LASER INSTRUMENTS FOR SURGERY.
5. EVALUATE THE STATUS OF THE DESIGN OF THE BEAM DELIVERY AND TARGETING SYSTEMS COMPRISING THE LASER INSTRUMENT FOR SURGERY. TO GIVE ADVICE UPON THE OPTIMAL DESIGN OF SYSTEMS AND TO OTHER APPLICATION-ORIENTED COMPONENTS.
6. ASSESS THE RESSOURCES NEEDED FOR UPGRADING THE BASIC TECHNOLOGIES AS PER ITEMS 1-3 AND 5 AND DISCUSS WITH RELEVANT AUTHORITIES THE PRIORITY RATES AND POSSIBLE CO-OPERATION WITH INSTITUTIONS DEALING WITH SIMILIAR TECHNOLOGIES.
7. OUTLINE, ON THE BASIS OF AQUIRED DATA, THE FLOWCHART OF UPGRADING THE TECHNOLOGIES OF MANUFACTURING THE MAJOR COMPONENTS, OF ASSEMBLING, TESTING AND APPLICATION PROCEDURES.
8. TO ACHIEVE AN AGREEMENT WITH NCRIEO AUTHORITIES AND OTHER RELEVANT PERSONS, UPON THE JOINT PROGRAMME OF ACTIONS AIMED IN DESIGN AND MANUFACTURING OF LASER SURGICAL INSTIRUMENTS BASED ON ND:YAG LASERS.

THE CONSULTANT IS ALSO EXPECTED TO PREPARE FOR HIS DEBRIEFING SESSION IN UNIDO THE DETAILED FINAL REPORT, SETTING OUT THE RECOMMENDATIONS OF HIS MISSION. THIS REPORT SHOULD THEN BE USED AS A BASELINE FOR THE FORTHCOMING UNDP/UNIDO PROJECT ACTIVITIES WITH IMMEDIATE OBJECTIVE TO ESTABLISH AND STRENGTHEN THE INSTITUTIONAL INFRASTRUCTURE CAPABLE TO MANUFACTURE LASER-BASED MEDICAL INSTRUMENTS FOR SURGERY.

QUALIFICATIONS: UNIVERSITY BACKGROUND IN PHYSICS/ ELECTROPHYSICS/ APPLIED OPTICS WITH MINIMUM 15 YEARS OF EXTENSIVE PRACTICAL AND SCIENTIFIC EXPERIENCE IN SOLID-STATE LASER TECHNOLOGY, DESIGN AND MANUFACTURING, KNOWLEGE OF STATE-OF-THE-ART IN LASER SURGERY IS A MUST.

LANGUAGE: ENGLISH

ANNEX 2

Schedule of Mission Activity

Fr	09.02	AM - arrival to Beijing PM - meeting with UNDP representatives Mrs.Li and Mr.Zhan, discussion on the Project contents
Sa	10.02	Meeting with NCRIEO authorities (Director Deputy Dr. Qiu), survey of Prodoc draft prepared by NCRIEO
Mo	12.02	Visit to NCRIEO crystal growth and optical coating laboratories.
Tu	13.02	Visit to the ophthalmological centre; acquaintance with the mechanical and optical workshops. Discussions on the project contents
We	14.02	Meeting with UNDP representatives Mrs.Li and Mrs Raab-Skapska to discuss the project conception
Th	15.02	Visit to Beijing An-Shen Hospital, Laser Surgery Department
Fr	16.02	Preparation of the Prodoc draft
Sa	17.02	Visit to the renovated laboratories of NCRIEO, acquaintance with the laser design and assembly. Preparation of the Joint Technical Minutes and revised Prodoc draft
Mo-Tu	19-20.02	Preparation of the reviser Prodoc draft
Th-Tu	22-27.02	Preparation of the final version of the Prodoc draft
Mo-Tu	26-27.02	Meetings with CICETE and NCRIEO representatives(Mr. Li, Mr. Zhan, Dr.Qiu, and others), discussions about optimal ways for the project implementation.

We	28.02	Technical meeting with UNDP representatives Mr. Behrstock, Mr.Murata, Mr. Zhen, Mrs Raab-Skapska for the discussion on the Project Document.
Th	01.03	Departure from Beijing.

ANNEX 3

JOINT TECHNICAL MINUTES

Beijing, 25.02.1990.

1. This Technical Minutes summarize the rezults of discussions between representatives of NCRIEO Mr.Qiu (NPD, Deputy Director of NCRIEO) and Mr.Li (Deputy NPD, Deputy Chief of Laser Research Department) and Dr. Soms (UNIDO expert) concerned the technical aspects of the draft Project Document (Project No: CPR/89/005, "Manufacturing Technology of YAG Lasers for Medical Equipment").

2. Dr. Soms was given the opportunity to get aquaintance with:

- the laboratory and equipment for Kr- and Xe- pump lamps manufacturing;
- laser crystals (Nd:YAG) growth laboratory;
- optical coatings laboratory;
- mechanical and optical workshops;
- optical testing and control laboratories;
- medical laser laboratory and assembly room;
- to observe the design and specific constructive features of medical laser equipment produced by NCRIEO, namely laser for surgery model JY-C, CW multimode up to 100 W, with the fiberoptics facility, and laser for ophtalmology model JUZ-1, Q-switched single-mode 40 mJ, coupled with the slot-lamp ophtalmoscope;
- to visit Beijing An-Zhen Hospital (Beijing Health, Lung and Blood Vessel Medical Centre) and Xie-He Hospital, and to get aquaintance with the operational rooms and corresponding equipment that uses the medical lasers manufactured by NCRIEO for surgical and ophtalmological operations, respectively.

Dr. Soms was shown also the modernized and renovated rooms and equipment for manufacturing and assembly other products, and mode-lock solid-state laser equipment under other areas of NCRIEO activities.

The extensive discussions were done between Dr. Soms and NCRIEO representatives conserning the context of the Project Formulation Framework and the Project Document draft.

3. The conclusions about the mentioned-above topics are as follows:

3.1 NCRIEO has all required technological lines that are necessary to develope, design and manufacture both solid-state (Nd:YAG) lasers for medical use (except the fiber-optical waveguides, supplied at NCRIEO by contracts) and corresponding electronic environment (as control and monitoring systems).

3.2. NCRIEO has some experience in medical Nd:YAG lasers design and cooperation with medical institutions in China. NCRIEO provides post-sell service of manufactured equipment and has opportunity of necessary feed-back for improvements and renovations of equipment.

3.3. The level of technologies for manufacturing the basic laser elements (namely: -lamps; -Nd:YAG crystal growth; -optical coatings deposition; - laser rods grinding and polishing), used in NCRIEO, corresponds the end of 60-- beginning of 70"- years.

The priority range of required improvements corresponds to the listed above order.

The retrospective analysis of failures has given the possibility to evaluate the relative share of above-mentioned causes (from 100 items of equipment that were produced in 1986-1990 yy. during their exploitation almost every laser needed the lamp change; from 69 failures in 34 cases that was due to irreversible drop of pumping energy conversion efficiency in the laser rod, and in 31 cases the damage of coatings).

3.4. The design, manufacture and assembly of medical lasers in NCRIEO do not satisfy up-to-date level and conditions.

Taking that into account, it was found necessary to enlarge the activity concerning output 4 in Project Document draft, namely "Basic Laser Unit prototype for medical applications designing and manufacturing technologies", with the mutual concern about indispensable internaional assistance for this activity. Thecreation and testing of medical laser prototype with the use of modern elements (which technologies to we developed according the Outputs 1,2,3) and up-to-date approach to its design and manufacture will provide the decisive and quatnitative check up of the effectiveness and the result of all Project activities.
Medical laser design should be resulted not only in improved efficiency and reliability but also in the solving the problem of friendly-to-user (here surgeons and operational medical nurses) software and hardware; existing model of laser for surgery does not correspond such requirements. Medical laser prototype should be oriented to and compatible with the most novel approaches in laser surgical technique (here - the contact surgery) in order to represent the world level at the end of project.

UNIDO Expert
Dr. Soms

NPD, NCRIEO Deputy Director
Dr.Qiu Honghua