Award 63440
Proj. 80515

United Nations Development Programme

Country: China

Project Document

Project Title:	Demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd.
UNDAF Outcome(s):	Government and other stakeholders ensure environmental suitability, address climate change, and promote a green, low carbon economy
Expected CP Outcome(s):	Low carbon and other environment sustainable strategies and technologies are adapted widely to meet China's commitments and compliance with Multilateral Environment Agreements.
Expected Output(s):	To provide an environmentally safe and cost-effective alternative for enabling replication of this technology in similar applications and enterprises in the Solvents Sector in China contributing to the viability of a large number of enterprises in this sector, and result in reductions in HCFC consumption of 3.1 ODP tones.
Executing Entity:	Foreign Economic Cooperation Office, China Ministry of Environmental Protection (FECO/MEP)
Implementing Agency:	United Nations Development Programme (UNDP)

Project Summary

The XIXth Meeting of the Parties to the Montreal Protocol in September 2007, through its Decision XIX/6, adopted an accelerated phase-out schedule for HCFCs. The first control is the freeze on production and consumption of HCFCs from 01 January 2013, at the Baseline Level (average of 2009 and 2010 consumption levels). The other control steps are reduction of 10% by 2015, reduction of 35% by 2020, reduction of 67.5% by 2025, reduction of 100% by 2030, allowance of 2.5% of baseline (annual equivalent) for period 2030-2040 and complete phase out by 2040. China is a party to the Montreal Protocol and must comply with the above targets.

During the 64th Meeting of the Executive Committee, the demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd. (CPR/SOL/64/DEM/511) was approved by the Executive Committee with UNDP as the implementing agency. Total approved funding from MLF was US $ 352,051. Additional funding of US$ 205,616 has been approved as a bilateral cooperation component with the Government of Japan, with UNDP as the implementing agency. This demonstration project, upon successful completion, will establish the suitability of iso-paraffin and siloxane (KC-6) technology as a viable replacement to HCFC-141b technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co, which will provide an environmentally safe and cost effective alternative for enabling replication of this technology in similar applications and enterprise in the Solvent Sector in China contributing to the viability of a large number of enterprises in this sector, and result in reductions of HCFC consumption of 3.1 ODP tones, contributing to compliance with the 2013 and 2015 control targets. It will also lead to net annual direct emission reductions of 18,980 tonnes CO2-eq. The implementation of the project will follow the rules and procedures of National Execution (NEX). The Performance Based Payment (PBP) mechanism will be applied for the implementation.

Programme Period:	**2011 – 2013**	Total resources required	557,667US$
Key Result Area (Strategic Plan):		Total allocated resources:	
		• Regular	
Atlas Award ID:		• Other:	
		o MLF	352,051US$
Start date:	1 December 2011	o Japan	205,616US$
End Date	31 May 2013		
Management Arrangements	NEX	In-kind Contributions	-

Agreed by FECO/MEP:

Agreed by UNDP: Napoleon Navarro

LIST OF ABBREVIATIONS

CFC Chloro Fluoro Carbons
HCFC Hydro Chloro Fluoro Carbons
CP Country Programme
CTC Carbon Tetra Chloride
ExCom Executive Committee of the Multilateral Fund
FECO Foreign Economic Cooperation Office
GWP Global Warming Potential
HCFCs Hydrochlorofluorocarbons
IA Implementing Agency
MEP Ministry of Environmental Protection
MLF Multilateral Fund for the Implementation of the Montreal Protocol
MOP Meeting of Parties to the Montreal Protocol
MP Montreal Protocol
MT Metric Tonnes
ODP Ozone Depleting Potential
ODS Ozone Depleting Substances
PBP Performance Based Payment
SBAA Standard Basic Assistance Agreement
UNDP United Nations Development Programme

I. SITUATION ANALYSIS

1. OBJECTIVE

The objective of this project is to assist Government of China implement the "Demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd." (hereinafter Solvent Demonstration project) .

2. BACKGROUND

2.1 ODS Phase Out in China

China signed Vienna Convention for the Protection of the Ozone Layer in June 1989, Montreal Protocol on Substances that Deplete the Ozone Layer (hereinafter Montreal Protocol) in June 1991. As of May 2010, China has ratified all amendments to the Montreal Protocol. Chinese government compiled and approved "Country Program for Phase-out of Ozone Depleting Substances" (hereafter Country Program) in January 1993 and established phase-out strategies for major sectors of ODS production and consumption in 1995. In November 1999, Chinese Government updated the Country Program. According to Country Program, with the support of Multilateral Fund and international institutions, China has conducted more than 400 projects and 18 sector plans including chemical production sector, Automobile Air-conditioner Sector, Tobacco Sector, Industrial and Commercial Refrigeration and Air Conditioning, Extinguishing Sector, Solvent Sector, Household Appliance, Foam Sector etc. to phase out production and consumption of CFCs, Halons, CTC, TCA and Methyl Bromide subsequently. With two decades of hard work, China had completed the phase-out of the production and consumption of CFCs and Halons on July 1st 2007, two and a half year earlier than the phase-out schedule under Montreal Protocol. Until January 1st 2010, except for essential use, Chinese Government had completely eliminated the production and consumption of CFC, Halons, CTC and TCA (5 year ahead the schedule) to meet the requirement of Montreal Protocol, which is an outstanding contribution to Ozone Layer protection.

2.2 Evolution of HCFC Phase-out Management Plans

HCFCs, which have Ozone Depleting Potential (ODP) up to 15% of that of CFCs, are also classified as controlled substances under Annex-C, Group-I of the Montreal Protocol. HCFCs, therefore, have use restrictions and would eventually have to be phased-out. Initially, for developing countries, the scheduled phase-out date for HCFCs was 1 January 2040 with an interim control measure of freezing HCFC production and consumption at 2015 levels from 1 January 2016.

The XIXth Meeting of the Parties to the Montreal Protocol in September 2007, through its Decision XIX/6, adopted an accelerated phase-out schedule for HCFCs. The first control is the freeze on production and consumption of HCFCs from 01 January 2013, at the Baseline Level (average of 2009 and 2010 consumption levels). The second control step is the reduction of 10% from the Baseline Levels on January 1, 2015. Subsequent control steps are 35% reduction by 2020, 67.5% by 2025, 97.5% by 2030 and complete phase out from January 1 2040. The decision also directed the Executive Committee of the Multilateral Fund to assist Article-5 Parties in preparation of HCFC Phase-out Management Plans (HPMP).

2.3 HCFC Phase-out Management Plan of China

Hydrochlorofluorocarbons (HCFCs) are classified as controlled substances under Annex-C Group-I of the Montreal Protocol and are subject to the adjusted control schedule for Article-5 countries; to freeze the HCFC production and consumption at baseline levels from 2013 and reduction of 10% from baseline levels from 2015. There are more than 30 categories of HCFCs controlled in Montreal Protocol. Currently, only six of them are produced in China: HCFC-22, HCFC-123, HCFC-124, HCFC-133a (mainly used as feedstock), HCFC-141b and HCFC-142b. In addition, HCFC-225 from foreign market is also consumed in China. The production and consumption of HCFCs in China is involved with 7 sectors: HCFC Production Sector, PU Foam Sector, XPS Foam Sector, Room Air Conditioning Sector, Industrial and Commercial Refrigeration and Air Conditioning Sector, Solvents Sector and Servicing Sector.

Solvent Demonstration Project

The major applications of HCFCs within the Solvents Sector in China include cleaning in the Medical, Metal (Compressors), Metal (Other), Electronics (LCD), Electronics (Precision), Electronics (Other) and Formulated Solvents sub-sectors. According to survey statistics, The HCFC consumption in the Solvents Sector in China was 4,394 metric tonnes in 2009.

The Medical Cleaning Applications sub-sector is important from a human health perspective and consumed about 1,700 metric tonnes of HCFC-141b in 2009, representing about 39% of the overall sector consumption. The sub-sector manufactures products that are applied widely and involve more than 400 enterprises. Since the 1980s, along with China's rapid economic development, the sub-sector has made great progress and maintained an average annual growth rate of over 15%, and China has thus become the world's leading medical macromolecular product manufacturer. According to statistics, in 2009, the gross sales in the sub-sector exceeded US$ 1.5 billion, 16% higher in real terms than a year earlier. The main products manufactured in this sub-sector include syringes, infusion sets, blood transfusion sets, various puncture instruments (e.g., hypodermic needles, scalp vein sets, blood collection needles, intravenous canulae, puncture needles, biopsy needles, etc.), catheters and other sanitary materials. The devices manufactured are siliconized to reduce friction and reduce the patients' pain; in addition, the silicification tooling used in the manufacturing of these devices needs regular cleaning, so as to prevent the tooling stained with silicone oil from polluting the joints of puncture instruments. The sub-sector comprises of a large number of SMEs with limited access to alternative technologies for HCFCs and their viability depends upon accessing suitable alternative technologies at the earliest. For these reasons, China has prioritized this sector and sub-sector for early interventions to meet the 2013/2015 targets.

To work out a cost-effective and sustainable alternatives to HCFC-141b technology that could be implementable in the large number of predominantly SMEs in the Medical Cleaning Applications sub-sector, the Solvent Demonstration project was prepared and submitted for the consideration of the 62nd Meeting of the Executive Committee after due review and endorsement by the Government. The Executive Committee approved the Solvent Demonstration project in 64th meeting in July 2011 at a funding level of US $ 557,667, including the funding of US$ 205,616 has been approved as a bilateral cooperation component with the Government of Japan, with UNDP as the implementing agency. The agreement between the ExCom and Government of China indicated the Solvent Demonstration project aims to phase out 3.1 ODP tons upon its completion.

II. STRATEGY FOR SOLVENT DEMONSTRATION PROJECT IMPLEMENTATION

The Solvent Demonstration project is designed for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd (hereinafter Zhejiang Kindly). Zhejiang Kindly is specialized in the manufacturing of disposable medical devices, particularly disposable needles. The enterprise is a member of the National Technical Committee for Standardization of Medical Injectors and also the National Technical Committee for Standardization of Infusion and Transfusion Sets and has been participating in drafting and revising over ten national and industrial standards. The enterprise has prior experience in implementing ODS phase-out. It was the first enterprise in the sub-sector to phase-out CFC-113. The detailed procedure of conversion from HCFC-141b to iso-paraffin and siloxane (KC-6) technology at Zhejiang Kindly has been explained in the Annex III.

The Solvent Demonstration project comprises the following interventions:

- Modification of needle assembly production lines
- Process adjustments
- Silicification fluid management
- Modification of silicification tooling lines
- Training and technical assistance
- Performance evaluation

III. TIME FRAME/MONITORING MILESTONES

Overall time plan for implementation of the project during the 15 months is given in the table below:

Table 1

MILESTONE/MONTHS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Start-up of project activities	X														
Project document signature	X	X													
Contracts signature		X	X												
Process and equipment design				X											
Equipment Procurement Technical Requirements Development				X											
Raw materials preparation for trial (Procurement, test and compounding of silicification fluid)							X								
Procurement and Manufacture of Equipment					X	X	X	X							
Equipment delivery and installation								X	X						
Training and Technical assistance								X	X	X					
Commissioning and trial runs									X	X	X				
Verification of Environmental protection, fire prevention and labor insurance									X	X	X				
Confirmation of Biocompatibility and Drug Compatibility									X	X	X	X	X	X	
Summary and Evaluation														X	X
Assessment and verification													.		X

IV. RESULTS AND RESOURCES FRAMEWORK

Table 2

Applicable Goal (UNDAF):	**Outcome:** Low carbon and other environment sustainable strategies and technologies are adapted widely to meet China's commitments and compliance with Multilateral Environment Agreements **Indicator:** Increased awareness among enterprises, especially SMEs, about corporate social responsibility and green work practices and technologies			
ATLAS Award ID:	00063440			
ATLAS Project ID:	00080515			
Intended Outputs	**Output Targets for 2011 to 2013**	**Indicative activities**	**Responsible Parties**	**Inputs (US $ 000)**
Output: To establish the suitability of iso-paraffin and siloxane (KC-6) technology as a viable replacement to HCFC-141b technology for cleaning in Solvent Sector and to reduce 3.1 ODP tones of HCFC. **Baseline:** The HCFC-141b consumption during 2009 at Zhejiang Kindly was 28.72 metric tonnes (3.1 ODP tonnes). **Indicator:** Successful completion of the conversion for HCFC-141b and meeting the reduction target of 3.1 ODP tonnes.	**Targets : 2011** Project Document signed. **Targets : 2012** - Contract with Zhejiang Kindly signed. - Completion of equipment installation. - Implementation of using iso-paraffin and siloxane (KC-6) technology for cleaning and silicification in the two production lines. **Targets : 2013** - Completion of conversion from HCFC-141b-based technology for cleaning and silicification in the two production lines in Zhejiang Kindly. - Completion of performance verification. - Meeting the reduction target at 3.1 ODP tons.	**Technical Assistance and Supporting Implementation** - Design the conversion - Training on process and safety - Performance verification and Technical assessment	FECO/MEP UNDP	101,014
		Implementation of Conversion - Signing Contract between FECO/MEP and Zhejiang Kindly - Equipment delivery and installation - Commissioning and trial runs	FECO/MEP	251,037
		Converted systems* running - Procurement of new materials - Running and Maintenance	FECO/MEP	205,616
		Grand total		**557,667**

Note: "*" This activity will be implemented in support of the funding of IOC from Japan government.

V. ANNUAL WORK PLAN

The table below presents the annual budget allocation during the project life cycle from 2011 to 2013.

Table 3

AWARD ID	00063440						
PROJECT ID	00080515						
Project Title	Demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd.						
Executing Agency	Foreign Economic Cooperation Office, China Ministry of Environmental Protection (FECO/MEP)						
ATLAS Activity	**Responsible Party**	**Source of funds**	**ATLAS Code**	**ATLAS Budget Description**	**2011**	**2012**	**2013**
Activity 1 : Technical Assistance and Supporting Implementation	FECO/MEP	63080	72100	Contractual Services	19,503	19,502	
	UNDP	63080	71200	International expert	8,000	-	-
Activity 2 : Implementation of Conversion	FECO/MEP	63080	72100	Contractual Services	152,523	152,523	
Activity 3: Converted system running	FECO/MEP	63080	72100	Contractual Services			205,616
	Subtotal				**180,026**	**172,025**	**205,616**
	Total						**557,667**

VI. MANAGEMENT ARRANGEMENT

6.1 Implementation Modality

The agreement between the Chinese government and the ExCom will serve as the framework within which the Solvent Demonstration project will be implemented. The project will be managed in accordance with National Execution (NEX) modality. The Government of China through its Foreign Economic Cooperation Office, Ministry of Environmental Protection (FECO/MEP) will be implementing project with support from UNDP. The MoU between UNDP and FECO/MEP which was signed on 8 January 2011 will serve as the guideline for the overall management on the project implementation. The Performance Based Payment (PBP) Mechanism will be applied for the implementation of National Coordination project as discussed in this ProDoc.

Under the PBP mechanism, the enterprise tasked to carry out the conversion would play the role as a key executer, which is responsible for all the activities related to the conversion (with supervision of the technical expertise team hired by FECO and/or UNDP), including but not limited to: product redesign, procurement of raw material, components, equipments and consulting services as per the budget allocation table, modification of production lines and product testing devices, etc., trial operation of production lines. The procurement shall be organized fully in line with the marketing principle and related laws and rules in China, so that the goods and services procured are high quality, most reasonable price and suitable for product line conversion through a fair, transparent and justified procedure, to make sure the new alternative technology applied feasibly and successfully. The detailed arrangement/requirement on procurement will be defined in the contract between FECO/MEP and the Executor (enterprises).

6.2 Roles and responsibilities

UNDP is serving as the implementing agency to supervise the implementation of the Solvent Demonstration project, specifically including the following:

- Providing assistance to ensure the smooth implementation through close coordination with FECO/MEP;
- Providing assistance on technical monitoring at Zhejiang Kindly, when required;
- Ensuring the submission of periodic implementation plans and reports to MLF accurately and on time;
- Monitoring the progress and carrying out supervision mission;
- Ensuring the Fund disbursed in accordance with the guidelines of the ExCom;
- Reporting the technical assessment to the ExCom.

FECO/MEP will be responsible for the overall implementation, coordination and management of the Solvent Demonstration project, specifically including the following:

- Coordinating with Zhejiang Kindly to finalize the conversion plan;
- Ensuring the smooth implementation of conversion;
- Conducting technical monitoring to ensure the selected alternative technology has been appropriately applied;
- Facilitating performance verification and financial audit as required;
- Preparing the implementation plan and progress reports as per provision of the agreement between the Chinese government and the ExCom, and requirement from UNDP;

- Implementing, supervising and monitoring the conversion activities to ensure meeting the reduction target.

Zhejiang Kindly Medical devices Co.Ltd is the beneficiary company in this project. The company's roles and responsibilities will be fully defined in the contract with FECO/MEP.

6.3 Payment Schedule and Indicators

Payment Schedule for Solvent Demonstration Project

Table 4

Payment Date (Indicative)	**Disbursement (US$)**	**Indicators/Milestones**
First disbursement No later than 15 Dec 2011	172,026	- Project Document is finalized and signed between FECO/MEP and UNDP.
Second disbursement No later than 30 Sep 2012	172,025	- Completion of equipment installation;
Third disbursement No later than 31 May 2013	205,616	- Completion of Performance Verification and Technical Assessment
	549,667	

VII. MONITORING FRAMEWORK AND EVALUATION

7.1 Verification & Monitoring

The activities of Verification &Monitoring include the following:

a) Performance Verification:

Before each payment, FECO will invite independent experts to verify whether the set milestones related to the payments have been met satisfactory. The verification reports will be submitted to UNDP as the main supporting documents for the respective payment requests. The verification must be accepted by UNDP before any project payments.

The Performance Verification shall establish:

- If the target of HCFC-141b phase out which is defined in the project approved by the ExCom has been achieved.
- If Zhejiang Kindly has completed the conversion as planned.
- If the alternative technology has been applied in Zhejiang Kindly as agreed.
- If the technical assistance has been appropriately conducted and obtained achievements by Zhejiang Kindly which are defined in the conversion plan.

b) Technical Assessment

Before the last installment of payment, FECO and UNDP will invite independent experts to verify whether the selection and application of alternatives in practice are suitable and feasible. The assessment report will be submitted to FECO and UNDP.

c) Financial Audit:

NEX Audit will be organized by UNDP during the project implementation upon UNDP's audit arrangement in the project years. For any issue identified during the auditing process, FECO shall take corresponding correction/improvement measures as per the audit findings and recommendation. Meanwhile, the payment will be suspended depending on the nature of the issues concerned until the acceptable/satisfactory results are worked out.

The financial audit aims to verify:

- If the project fund has been appropriately applied which are in line with the Project Document between UNDP and FECO.
- If the project fund has been appropriately disbursed in the enterprise in accordance with the requirement defined in the contracts between FECO and the enterprises.
- If the project has achieved certain progress which are defined in the project document and the annual work plan.

d) Review Meetings, reports, missions

Quarterly Review and Annual Review Meeting will be organized by FECO and participated by the company if necessary.

Quarterly/Semi-annual Project Review Reports and a final Project Report will be submitted to UNDP at least 10 days before the review meetings and by the end of project operation by 2013.

FECO and UNDP will organize a joint Monitoring and Evaluation mission to the Project executer during this project operation. The mission can be combined with the verification mission accordingly. The M&E schedule will basically follow the timeline of payment schedule.

e) Documents record.

A copy of the signed contract between FECO/MEP and the project executor (Company) shall be filed for record at UNDP CO.

7.2 Quality Management for Project Activity Results

Table 5

OUTCOME: To provide an environmentally safe and cost-effective alternative for enabling replication of this technology in similar applications and enterprises in the Solvents Sector in China contributing to the viability of a large number of enterprises in this sector, and result in reductions in HCFC consumption of 3.1 ODP tones.		
Output: The following outputs/activities contribute to achieving the outcome above: • The conversion is designed, planned, monitored and reported correctly and timely. • The conversion is implemented and completed as planned. • The converted system is running with alternative technology and HCFC phase out amount verified.		
Result 1	**The conversion is designed, planned, monitored and reported correctly and timely.**	Start Date: 1 Dec 2011 End Date: 31 May 2013
Purpose	Ensuring the smooth and successful conversion implementation.	
Description	• Prepare the implementation plan. • Finalize of Project Document. • Provide technical assistance as needed during the project implementation.	
Quality Criteria	**Quality Method**	**Date of Assessment**
Implementation plan and the deliverables under TA contracts are is submitted on time.	Deliverables of TA contracts and monitoring and reporting conducted on time.	After each contract, no later than 31 May 2013
Result 2	**The conversion is implemented and completed as planned.**	Start Date: 1 Mar 2012 End Date: 1Mar 2013
Purpose	Ensuring the accurate and timely conversion of production line.	
Description	• Finalize conversion plan; • Complete equipment procurement and installment; • Complete commissioning and trial runs; • Achieve HCFC-141b phase-out as defined in the project approved by the ExCom.	
Quality Criteria	**Quality Method**	**Date of Assessment**
Contract between FECO/MEP and Zhejiang Kindly signed	Conversion contract	1 Mar 2012
Conversion plan developed	Conversion plan	31 Mar 2012
Equipment installed	Equipment procurement and installation	15 Jul 2012
Trial run of	Verification report	31 Dec 2012

production line		
Result 3	**The converted systems is running with alternative technology and HCFC phase out amount verified**	Start Date: 1 Jan 2013 End Date: 31 May 2013
Purpose	Successfully demonstrating the iso-paraffin and siloxane (KC-6) technology deployed for phasing-out HCFC-141b at Zhejiang Kindly.	
Description	• Verify converted system running and production processes. • Undertake and approve a technical assessment report and establishment of the suitability of iso-paraffin and siloxane (KC-6) technology as a viable replacement to HCFC-141b technology for cleaning and silicification in Medical devices sub-sector in Solvent Sector	
Quality Criteria	**Quality Method**	**Date of Assessment**
Conversion Performance Verification	Performance verification report	31 May 2013
Technical feasibility Assessment	Technical assessment report	31 May 2013

VIII. LEGAL CONTEXT

This project document shall be the instrument referred to as such in Article 1 of the Standard Basic Assistance Agreement (SBAA) between the Government of the People's Republic of China and the United Nations Development Programme, signed by the parties on 29 June 1979.

Consistent with the Article III of the SBAA, the responsibility for the safety and security of the executing agency and its personnel and property, and of UNDP's property in the executing agency's custody, rests with the executing agency.

The executing agency shall:

a) put in place an appropriate security plan and maintain the security plan, taking into account the security situation in the country where the project is being carried;
b) assume all risks and liabilities related to the executing agency's security, and the full implementation of the security plan.

UNDP reserves the right to verify whether such a plan is in place, and to suggest modifications to the plan when necessary. Failure to maintain and implement an appropriate security plan as required hereunder shall be deemed a breach of this agreement.

The executing agency agrees to undertake all reasonable efforts to ensure that none of the UNDP funds received pursuant to the Project Document are used to provide support to individuals or entities associated with terrorism and that the recipients of any amounts provided by UNDP hereunder do not appear on the list maintained by the Security Council Committee established pursuant to resolution 1267 (1999). The list can be accessed via http://www.un.org/Docs/sc/committees/1267/1267ListEng.htm. This provision must be included in all sub-contracts or sub-agreements entered into under this Project Document.

In addition, the following types of revisions may be made to this Project Document with the signature of the UNDP resident representative only, provided he or she is assured that the other signatories of the Project Document have no objections to the proposed changes:

1. Revision in, or addition of, any of the annexes of the Project Document;
2. Revisions which do not involve significant changes in the immediate objectives, outputs or activities of the project, but are caused by the rearrangement of the inputs already agreed to or by cost increases due to inflation; and
3. Mandatory annual revisions that rephrase the delivery of agreed project inputs, or reflect increased expert or other costs due to inflation, or take into account agency expenditure flexibility.

IX: ANNEXES

ANNEX-I: Risk Analysis

ANNEX-II: Final version of Solvent Demonstration Project Document approved by the 64th Excom)

ANNEX- III: Incremental Capital Costs

ANNEX- IV: Incremental Operating Costs

ANNEX-I

RISK ANALYSIS

Description	Date identified	Type	Impact and Probablity (Low 1 to High 5)	Counter Measures	Owner
Delay in completion of project deliverables such as conversion plan, progress report and verification report to MLF etc.	Project initiation date	Operational	Probability - 3 : Impact - 4	Close coordination with FECO/MEP and periodic monitoring of project tasks. Facilitating timely completion of tasks.	FECO/MEP UNDP
Delay in confirming test on alternative solvent's biocompatibility, drug compatibility and silicification qualities.	Project initiation date	Technical	Probability - 3 : Impact - 4	Coordination with the beneficiary company in early submission of confirming test with sampled products from trial production before the conversion completion.	FECO/MEP UNDP
Delay in commissioning and trial runs.	Project initiation date	Operational	Probability - 3 : Impact - 4	Consultation with specialist technical experts on technical options, closely monitoring technical developments.	FECO/MEP UNDP

ANNEX-II

MULTILATERAL FUND FOR THE IMPLEMENTATION OF THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER

PROJECT COVER SHEET

COUNTRY: CHINA

PROJECT TITLE:

Demonstration project for conversion from HCFC-141b-based technology to iso-paraffin and siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd.

BILATERAL AGENCY:

Government of Japan

EXECUTING AGENCY:

UNDP

NATIONAL COORDINATING AGENCY: Foreign Economic Cooperation Office, Ministry of Environment Protection

LATEST REPORTED CONSUMPTON DATA FOR ODS ADDRESSED IN THE PROJECT:

A. Article-7 Data (ODP Tonnes for 2009):

ANNEX-C, GROUP-I SUBSTANCES (HCFCS)	17,997.68

B. Country Programme Sectoral Data (ODP Tonnes for 2009):

Substance	Total
HCFC-22	11,030.80
HCFC-141b	5,535.50
HCFC-142b	1,417.68
Others	13.70

ODS CONSUMPTION REMAINING ELIGIBLE FOR FUNDING (ODP Tonnes) :	N/A

CURRENT YEAR BUSINESS PLAN:	Included

PROJECT DATA

Sector:	Solvents		
Sub-sector:	Medical Cleaning Applications		
ODS use in sector (2009 ODP tonnes):			480
ODS use in sub-sector/application (2009 ODP tonnes):			187
Project impact (ODP tonnes):			3.1
Project duration:			18 months
Project costs:	Incremental Capital Costs:	US$	320,046
	Contingencies:	US$	32,005
	Incremental Operating Costs:	US$	205,616
	Total Costs:	US$	557,667
Local ownership:			100%
Exports to non-A5 countries:			0%
Requested grant:			**557,667**
Cost-effectiveness (US$/kg-ODS):			20.05
Bilateral cooperating agency support costs (13% up to US$ 500,000, 11% thereafter):		US$	71,343
Total cost to Multilateral Fund:		US$	629,010
Status of counterpart funding (Yes/No):			Yes
Project monitoring milestones included (Yes/No):			Yes

PROJECT SUMMARY

This demonstration project, upon successful completion, will establish the suitability of iso-paraffin and siloxane (KC-6) technology as a viable replacement to HCFC-141b technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd. The project covers development of the process technology, modification of manufacturing lines, process adjustments, silicification fluid management, evaluation of needle silicification and cleaning effects, confirmation of biocompatibility and drug compatibility, trials, certification, technical assistance and training.

Impact: The successful implementation of this demonstration project will provide an environmentally safe and cost-effective alternative for enabling replication of this technology in similar applications and enterprises in the Solvents Sector in China contributing to the viability of a large number of enterprises in this sector, and result in reductions in HCFC consumption of 3.1 ODP tonnes, contributing to compliance with the 2013/2015 control targets. It will also lead to net annual direct emission reductions of 18,980 tonnes CO_2-eq.

Prepared by: UNDP in consultation with Japan, FECO and industry **Date:**

Demonstration project for conversion from HCFC-141b technology to Isoparaffin and Siloxane (KC-6) technology for cleaning in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd.

Objective

The objective of this demonstration project is to establish the suitability of iso-paraffin and siloxane (KC-6) technology as a viable replacement to HCFC-141b technology for cleaning/silicification in the manufacture of medical devices at Zhejiang Kindly Medical Devices Co. Ltd.

Sector Background

The Solvents Sector is characterized by emissive use of HCFCs. The major applications within the Solvents Sector in China include cleaning in the Medical, Metal (Compressors), Metal (Other), Electronics (LCD), Electronics (Precision), Electronics (Other) and Formulated Solvents sub-sectors. The HCFC consumption in the Solvents Sector in China was 4,394 metric tonnes in 2009.

The Medical Cleaning Applications sub-sector is important from a human health perspective and consumed about 1,700 metric tonnes of HCFC-141b in 2009, representing about 39% of the overall sector consumption. The sub-sector manufactures products that are applied widely and involve more than 400 enterprises. Since the 1980s, along with China's rapid economic development, the sub-sector has made great progress and maintained an average annual growth rate of over 15%, and China has thus become the world's leading medical macromolecular product manufacturer. According to statistics, in 2009, the gross sales in the sub-sector exceeded US$ 1.5 billion, 16% higher in real terms than a year earlier.

The main products manufactured in this sub-sector include syringes, infusion sets, blood transfusion sets, various puncture instruments (e.g., hypodermic needles, scalp vein sets, blood collection needles, intravenous canulae, puncture needles, biopsy needles, etc.), catheters and other sanitary materials. The devices manufactured are siliconized to reduce friction and reduce the patients' pain; in addition, the silicification tooling used in the manufacturing of these devices needs regular cleaning, so as to prevent the tooling stained with silicone oil from polluting the joints of puncture instruments.

The sub-sector comprises of a large number of SMEs with limited access to alternative technologies for HCFCs and their viability depends upon accessing suitable alternative technologies at the earliest. For these reasons, China has prioritized this sector and sub-sector for early interventions to meet the 2013/2015 targets.

Rationale for the Demonstration Project

The Medical Cleaning Application sub-sector is not only important from the human health perspective, but it also uses HCFC-141b as a component of cleaning technology, that is entirely emissive. HCFC-141b also has the highest ODP among HCFCs under consideration. Cost-effective and sustainable alternatives to HCFC-141b technology that could be implementable in the large number of predominantly SMEs in the sub-sector are either not available in the short-term or will need to be developed and demonstrated. Taking into account the special nature of medical devices and their direct impact on health, caution needs to be exercised in promoting alternatives.

An actual demonstration on a needle assembly line and a silicification tooling cleaning line, summarizing experiences and lessons learnt, confirming biocompatibility, drug compatibility and silicification qualities in a selected credible enterprise, would provide the necessary confidence to the sub-sector to adopt the alternative more widely and safely with full knowledge of the impacts.

The experience from the demonstration project will not only hold effective demonstration and reference value for puncture instruments, but also can be potentially extended to all medical macromolecular fields that need to use silicone oil solvent. The implementation of this project will be of value and significance for cost-effective phase-out of HCFC-141b in the Medical Cleaning Application sub-sector in China and towards the achievement of China's compliance with the accelerated HCFC phase-out control schedule.

Enterprise Background

Zhejiang Kindly Medical Devices Co. Ltd. is a wholly Chinese-owned enterprise established in 1987. It is one of the four subsidiary enterprises of the Shanghai Kindly Enterprise Development Group Ltd ("KDL").

The enterprise is specialized in the manufacturing of disposable medical devices, particularly disposable needles. The main products manufactured are hypodermic needles, scalp vein sets, anesthesia needles, dental needles, Huber needles, puncture needles, blood collection needles, irrigation needles, AV fistula needles, IV catheters and insulin pen needles. The enterprise has a complete mechanized production line from jointing capillary, extruding, grinding, auto-assembly for hypodermic needles to packaging with an annual capacity of 3 billion pieces for hypodermic needles, 0.5 billion pieces for scalp vein sets, blood collection needles , dental needles and other needles, and 7 billion pieces for different canulas. In 2009, the enterprise accounted for about 45% of the domestic output for these products. The enterprise emphasizes product quality and quality management. It has ISO 9002-EN 46002 certification since 1998 and also has CE certification. The hypodermic needles manufactured by the enterprise have been approved by FDA on site audit. The enterprise is a member of the National Technical Committee for Standardization of Medical Injectors and also the National Technical Committee for Standardization of Infusion and Transfusion Sets and has been participating in drafting and revising over ten national and industrial standards.

The rationale for selecting Zhejiang Kindly Medical Devices Co. Ltd. for implementing this demonstration project is as below:

- The enterprise is one of the best organized in the sub-sector with sound technical and financial standing and has shown willingness to undertake this demonstration
- The enterprise has prior experience in implementing ODS phase-out. It was the first enterprise in the sub-sector to phase-out CFC-113.
- The enterprise has been spearheading research and development as well as leading in corporate social responsibility initiatives for adopting environment-friendly technologies
- The enterprise heads the industry association and has been instrumental in cooperating with FECO/MEP, local governments and industry partners for technology information dissemination activities
- By taking the lead in HCFC phase-out, the enterprise will guide the rest of the sub-sector effectively to adopt alternatives and to contribute to China's HCFC phase-out targets.

Based on the above considerations, Zhejiang Kindly Medical Devices Co. Ltd. was considered to be the most appropriate candidate for carrying out this demonstration.

Technology

Current Technology

When CFC-113 was being replaced, initially KC-3000 was introduced, a mixed solvent whose main component is HFC-365mfc (see below for more details). However, because of the relatively high cost of KC-3000, KC-3000C, developed by Beijing Aerospace Technology Innovation Co., Ltd., came into widespread use. KC-3000C is a derivative of KC-3000 and is based on HCFC-141b (65% content). KC-3000C does not contain halogenated hydrocarbon; as a silicone oil solvent, its boiling point, surface tension and viscosity indicators are acceptable and its cost was very competitive, so it was an ideal substitute for CFC-113. KC-3000C is currently the most widely used solvent in the medical device industry. Zhejiang Kindly Medical Devices Co. Ltd., presently uses KC-3000C as a silicone oil solvent.

Overview of alternatives

Several alternative technologies for HCFCs such as HFE-7100, HFC-365mfc, Hydrocarbons, Alcohols, Low molecular weight halohydrocarbons, etc., are available or under development. But in general, there has to be a trade-off between solvent properties, costs, toxicity issues and flammability issues. Some of the important currently available alternatives for HCFCs are tabulated below:

Solvent Option	ODP	GWP	Remarks
HFC-4310	0	1,300	HFC-4310 is one of the Vertrel® series solvents launched by the US DuPont Company, with decafluoropentane as the principal component. It is non-toxic and non-flammable. As a silicone oil solvent, the boiling point, surface tension and viscosity index are ideal. If HCFC-141b is taken as the benchmark for comparison, HFC-4310 shows poor effects of CO_2 emission reduction and its toxicity is higher than HCFC-141b. Moreover, it is expensive and the price is as high as US$ 70/kg
HFC-365mfc	0	840	While this option offers good solvent properties, with respect to HCFC-141b, it has a higher GWP. It is also flammable in the range of 3.5% - 9% by volume in air, thus safety becomes a significant obstacle. It is also more expensive than HCFC-141b with a cost of about US$ 22/kg.
KC-3000	0	750	KC3000 is a HFC-365mfc-based mixed solvent. It is compatible with most kinds of materials, not easily flammable, non-toxic and volatile and its chemical properties are stable. Its inadequacy is that it has a certain degree of flammability. The cost is about US$ 12/kg.
HFE-7100	0	480	HFE-7100 is a fluoride either based solvent launched by 3M® Corporation. It is noon-toxic, non-flammable and has a relatively low GWP. As a silicone oil solvent, its boiling point, surface tension, and viscosity index are ideal. Although its boiling point is higher than HCFC-141b, its latent heat of evaporation is 40% lower than HCFC-141b, therefore, when the needle tube and the outer sleeve are silicified, the solvent is easily volatile, leaving little residue. Its surface tension is 26% lower than HCFC-141b, but its silicone oil dispersion and coating properties are better than HCFC-141b. Its GWP is lower than HCFC-141b. However, its main disadvantage is its cost, which is in the range of US$ 60/kg.
KC-6	0	<20	KC-6 is a new generation of environment-friendly medical silicone oil thinner developed by Beijing Aerospace Technology Innovation Co., Ltd., in light of the actual situation of China's medical device industry. It is a combination of Siloxanes, Isoparaffin, etc. Its shortcomings are that it has certain degree of flammability, a high boiling point, and is less volatile as compared to the current technology. Its cost is favorable at about US$ 6.2/kg.

There are other alternatives available or under development. But due to either high GWP, flammability, performance, implementability or costs, they were not considered to be viable.

Selection

In order to select alternative technologies that are both friendly to environment and suitable for Chinese conditions, FECO/MEP has mobilized experts and representatives from industrial associations, enterprises and research institutes to set up a Committee of Technical Experts for HCFC Replacement Technologies for China's solvent sector. Several field investigations to various enterprises were made and a number of seminars were convened to discuss alternative technologies. The experts analyzed various alternatives from six aspects, namely, performance, environmental properties, safety, biocompatibility, drug compatibility and economy. Their key conclusion was imported alternative technologies are not appropriate for the silicone oil used by Chinese enterprises and their prices are too high to be acceptable by Chinese enterprises. KC-6, whose main components are Siloxane and Isoparaffin, basically meet the technical requirements of the sub-sector, thus having a promising prospect of replacing HCFC-141b. The major considerations were as below:

- KC-6 is a mixture, whose components are easily available on the market at favorable costs through domestic production
- KC-6 has a higher boiling point than HCFC-141b; as a solvent, it is less volatile and therefore has less dissipation and result in less consumption
- KC-6 exhibits good solvent properties for silicone oil, removing silicone oil from contaminated tools quite easily. The compound is clear and transparent, with good coating quality on the surface of needles;
- KC-6 has a zero ODP and very low GWP, thus it is environment-friendly.
- Due to its chemical stability and high flash point and boiling point, its comprehensive emission reduction and environmental benefits turn out to be much better than the HCFC-141b-based solvents currently used.
- The compound can be used as both the silicone oil thinner and the cleaning agent therefore allows relatively easy management of procurement, storage and handling.

From the analysis of current findings, it can be seen that KC-6 promises to have a good applicability in this sub-sector in China.

Impact

Use of KC-6 as an alternative solvent, would have the following impacts:

Safety

KC-6 is flammable, although it has a higher flash point. When it is used by the medical device industry in clean rooms, particular attention needs to be given to safety due to the accumulation of solvent vapors, and necessary precautions have to be taken.

Silicification performance

KC-6 has a higher boiling point; after silicification, its evaporation rate will be slower than HCFC-141b. In accordance with the current practice, as soon as the needles are siliconized, they will be turned the upside down. Thus if the solvent cannot be evaporated in time the silicification fluid will flow to the needle hub, causing the absence of silicone oil in the needle tip and the contamination of the needle hub and silicification tooling. In order not to reduce the output, hot air dryers will need to be installed on the assembly line.

Biocompatibility and drug compatibility

Puncture instruments are devices that enter human tissues and may come into contact with blood. As KC-6 is a mixed solvent, the biocompatibility and drug compatibility of Isoparaffin, which is one of its components, will need to be confirmed in order to ensure safe use on patients.

Demonstration and dissemination

KC-6 technology would be demonstrated on one needle manufacturing line and one silicification tooling line at Zhejiang Kindly Medical Devices Co. Ltd. to establish its applicability comprehensively, from performance, health, safety and environment standpoints. The Medical Cleaning Applications sub-sector within the Solvents Sector accounts for about 39% of the HCFC consumption in the Solvents Sector. Moreover, Zhejiang Kindly Medical Devices Co. Ltd. is a major player in this sub-sector.

Taking into account the special nature of medical devices, caution is called for in promoting its application. The experience needs to be properly summarized covering all lessons learnt in the implementation of the demonstration project, and in particular, confirming the biocompatibility, drug compatibility and silicification qualities. The results of the application of this technology will need to be appropriately disseminated in the sub-sector, to build confidence, acceptability and future replication for all needle assembly lines in this enterprise and other puncture instrument assembly lines of other enterprises that need silicone oil solvent and cleaning agent.

The demonstration project will thus hold significant and effective reference value for puncture instruments, but also can be extended to all medical macromolecular fields that need to use silicone oil solvent. The implementation of this project will be of significance towards the achievement of China's compliance with the HCFC phase-out targets.

Project Description

This demonstration project proposes to modify an automatic needle assembly line and an ultrasonic cleaning line at Zhejiang Kindly Medical Devices Co. Ltd. to provide a demonstration of KC-6 technology.

Baseline Situation

The summary of manufacturing lines, output and HCFC consumption as solvent in 2009 at Zhejiang Kindly Medical Devices Co. Ltd., is tabulated below:

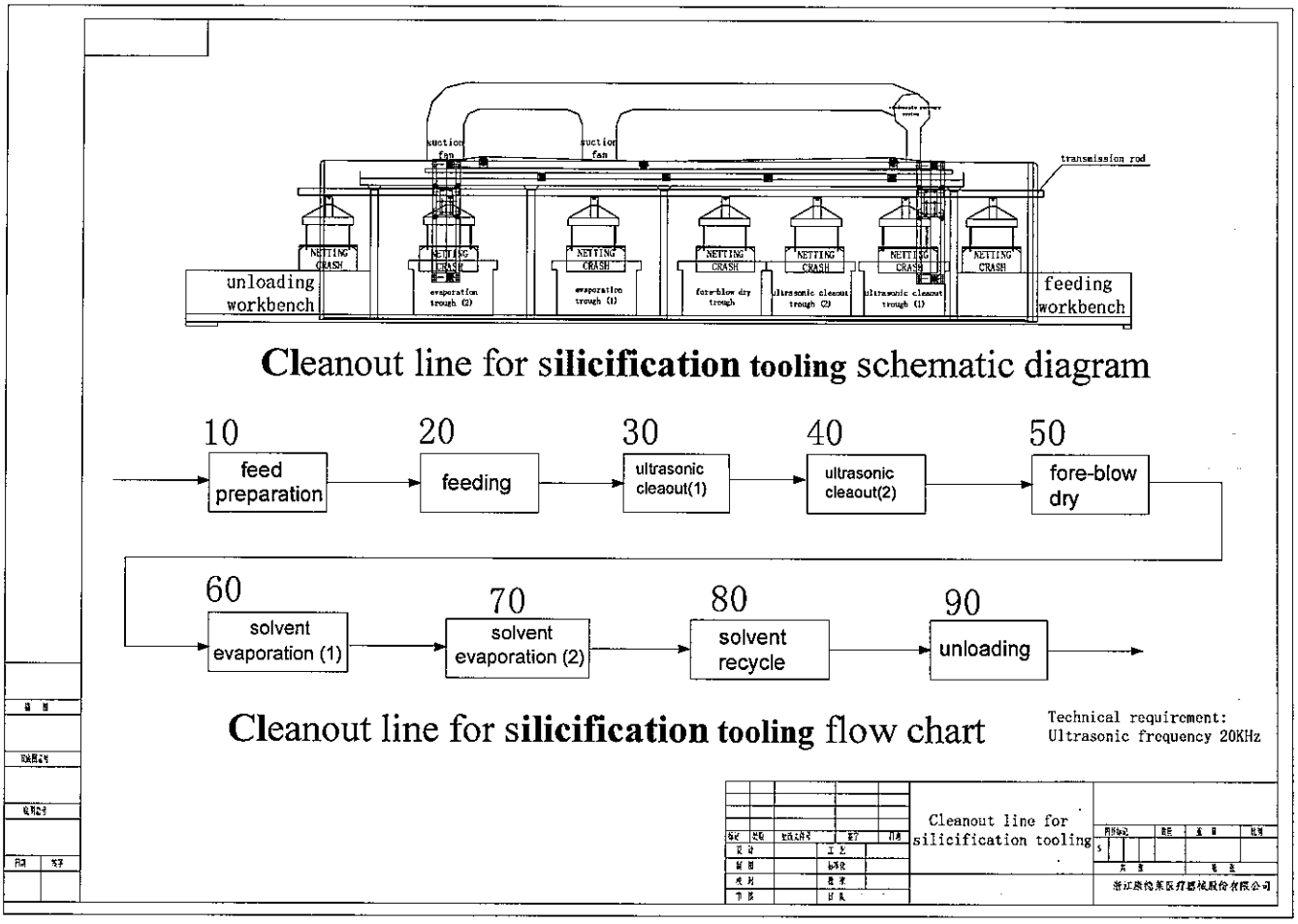
Manufacturing Line	Number of lines	Products	Installed Capacity (million units)	Actual Output (million units)	Avg. HCFC-141b consumption (kg/million units)	Total HCFC-141b consumption (metric tonnes)
Needle assembly	13	Needles	3,000	2,062.00	0.0377	77.74
Scalp vein sets	10	Scalp vein sets	800	630.40	0.0657	41.41
Variety needles	4	Plasma, blood needles	150	110.63	0.0464	5.14
Silicification ultrasonic cleaning	2	Silicification tooling	19,000 units of silicification tooling per cleaning, each line is cleaned 20 times annually			43.68
Total						**167.97**

The HCFC use figures are derived as 65% of the baseline KC-3000C figures.

One needle assembly line out of the total 13 lines is selected for the demonstration of KC-6 technology. The line is located in a Class 100,000 clean area. The assembly line was operationalized in 1998. The summary of the baseline details of this assembly line is tabulated below:

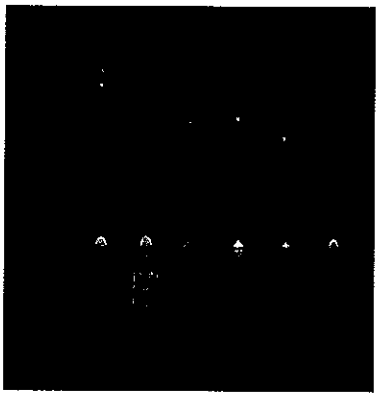
Manufacturing Line	Number of lines	Products	Installed Capacity (million units)	Actual Output (million units)	Avg. HCFC-141b consumption (kg/million units)	Total HCFC-141b consumption (metric tonnes)
Needle assembly	1	Needles	288	158.62	0.0377	5.98
Silicification	1	Silicification tooling	0.1151 kg HCFC-141b per line per cycle (20/y)			21.84
Total						**27.82**

Puncture instruments, such as medical needles, need to be coated with a layer of silicone oil on the blade and the tube. This process is called silicification. The purpose of silicification is to reduce frictional resistance and the patients' pain when the needle pierces the body. This process is completed at the silicification working station of assembly machines. Please see figure below for more details.

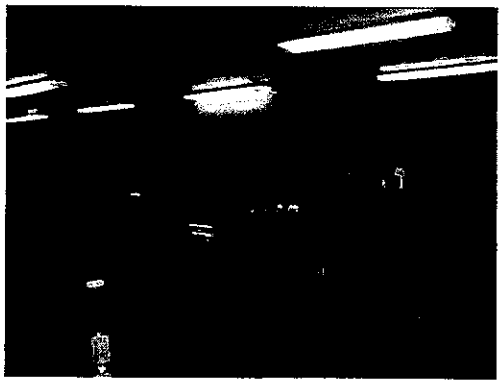


The current needle assembly line includes eight major production processes, i.e. feeding of needle hub, assembly of needle canula, gluing adhesive, curing (in a tunnel oven), silicification, feeding of protective cap, pressing protective cap, and unloading products. Each of these processes is

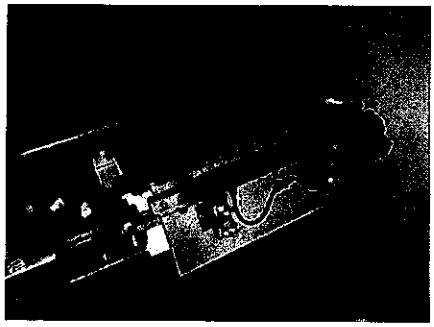
accomplished through special purpose-built automatic machines and devices of 1997-1998 vintage. The cleaning line for silicification tooling comprises of manual feeding of silicification tooling, cleaning (ultrasonic cleaning machine model 1024, 1.2 kW, 2005), airing and unloading. See pictures on following page.



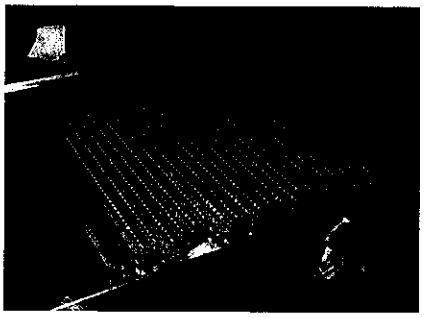
Needles



Needle assembly line



Silicification working station



Silicification tooling with needles

Proposed Changes

KC-6 has a higher boiling point and slight flammability. To address these issues, the demonstration project will involve modification of production lines, process adjustments, silicification fluid management, evaluation of needle silicification effects and the effects of silicification tooling cleaning, the confirmation of biocompatibility and drug compatibility, as well as related training and technical assistance.

Modification of Needle Assembly Line

Line	Proposed Changes
Needle Assembly Line	**Adjustment of the silicification process** Since KC-6 has certain flammability, in order to control the concentration of the clean room within flammable limits, it is necessary to install an explosion-proof local exhaust ventilation hood above the silicification tank to discharge as much as possible the volatile solvent vapors outside the clean room. All local ventilation hoods that have been installed in the clean room can be connected together to form a ventilation system during the entire phase-out in the enterprise in the future.

Line	Proposed Changes
Needle Assembly Line (Cont'd)	**Addition of hot air dryer** As KC-6 has a higher boiling point, the solvent cannot be volatilized in a timely way. So the silicification fluid will flow to the needle hub, causing the absence of oil in the needle tip and the pollution of the needle hub and silicification tooling.

	Therefore, in order to accelerate evaporation, a hot air drying process needs to be added after the silicification process.
	Technological adjustments Due to the use of a new solvent, the technical process of the whole assembly line has to be adjusted moderately: ***Production process***: Because of the addition of the hot air drying process, the operation speed of the assembly line, the quantity of tooling allocated and the work-piece making sequence need to be adjusted accordingly; ***Air conditioning technology***: In order to prevent the accumulation of solvent vapors in the clean room, it is necessary to increase the volume of outdoor air for dilution and to add fresh air, so that a positive pressure can be ensured in the clean room.
	Management of silicification fluid As a result of using a new solvent, it is necessary to adjust the silicification fluid management methods, including: compounding methods, the indicators and methods for controlling the concentration of fresh silicification fluid and the concentration and control indicators of silicification fluid in the tanks varying with the change characteristics of the duration of silicification, its control methods, testing methods of control indicator and equipment adjustments. A recovery system will be built to recover the solvent of the residual silicification fluid that has already lost effectiveness; explosion-proof security measures are taken to achieve a unified storage of the residue.
	Evaluation of needles silicification After using the new solvent, the effects of needle silicification shall be evaluated from two aspects: ***Appearance evaluation***: Evaluate the dispersion of silicone oil, oil amount at the needle tip and the pollution condition of the needle seat; ***Puncture force evaluation***: Use the needle sharpness tester for testing; investigate the magnitude of force, the peak value position and the waveform of force.

Modification of silicification tooling cleaning

Silicification tooling refers to a special kind of working station utensil (see picture) that is used on the assembly machines for puncture instruments. Needle assembly and silicification must be completed on this tooling. Each strip-shaped tooling contains 50 steel needle seats with unfinished needles. Each needle assembly machine usually has at least 600 such tooling. When the needles are siliconized, the tooling is contaminated by silicone oil, so it is necessary to clean the tooling on a regular basis. Otherwise, the silicone oil will stick on the inner bore of needle hubs and the outer surface. Accordingly, when needles are put on syringes, they will fall off automatically or the connection may not be secure. In case of continuous production, each tooling needs cleaning for every 15-20 days.

The original single-tank open-type ultrasonic cleaning machines are located in KDL's Class 100,000 clean room which was built in May 2005. Each cleaner could clean about 200,000 stripe-times of silicification tooling every year; in 2009 the consumption of KC-3000C was about 33.6 tonnes (equivalent to 21.84 metric tonnes of HCFC-141b). The machines in current use are all single-cylinder ultrasonic cleaners. Workers are needed to load and unload materials; after cleaning the materials have to be put on the shelf for drying. There are mainly 4 processes, i.e. loading, cleaning, drying and unloading. These machines will need to be modified due to the following:

The machines are not closed, so the operators will unavoidably have contact with solvents and inhale solvent vapors;

- There is no explosion-proof safety features and not suitable for the alternative solvent with slight flammability;

- There is no solvent recovery system, so the consumption is high. The cost will be increased when using the alternative solvent with higher price.

The following modifications are proposed:

- To realize mechanized operations to ensure minimum operator interference, human errors and exposure. The silicification tooling has a strip shape; when it is cleaned, a container is needed to hold it. Each container can hold 30 pieces silicification tooling. Thus a mechanical lifting device, instead of the manual operation of an operator, can be used to transfer automatically the containers between different working stations. In this case, the operator will not touch the solvent. These containers are an essential equipment to realize closed and mechanized operation. In addition, the containers must be designed not to block ultrasound penetration. Otherwise, the silicification tooling held within cannot get the impact of ultrasonic, and the effectiveness and efficiency of cleaning will be significantly reduced.

- To make the machine fully closed, and prevent operators from contact with solvents.

- To adopt the explosion-proof design, and select explosion-proof electrical appliances and equipment.

- To set up a solvent recovery system, so that solvent vapors in confined spaces and the polluted solvent residue can be recovered in time, so that solvent consumption can be reduced.

- After cleaning with the use of KC-6, an evaluation on the cleaning effects from the aspects of appearance and needle connection firmness needs to be conducted:

  - Appearance evaluation: Wipe the surface of the tooling with white paper, use a 10x magnifying glass to observe the surface of the white paper, and there should be no oil stains.
  - Connection firmness evaluation: Put a needle onto a cleaned silicification tooling, silicize the needle, and use a fastness tester to test its firmness to see whether the product is qualified.

- After modification, the silicification tooling cleaning lines will be adjusted according to the new features of KC-6 to ensure health, safety and environment

Confirmation of biocompatibility and drug compatibility

A testing center at the state level shall be entrusted to confirm whether the isoparaffin that remains after needle silicification and cleaning will have an impact on biocompatibility and drug compatibility.

Training

Training will be provided to the production, installation and maintenance personnel on the physical and chemical properties of KC-6, technical adjustments of modification processes and added processes, silicification fluid management, silicification effects, methods for cleaning effect evaluation, methods of operating newly-added equipment, machine operating parameters, machine maintenance procedures, precautions and safety measures, etc.

Project Costs

The total cost of the demonstration project is estimated at US$ 557,667.

The **incremental capital costs** of US$ 320,046 include capital investments required for the equipment and process changes and associated costs as described above. **Contingencies** amount to US$ 32,005 for adequate funding of incremental capital costs (10%). The **incremental operating costs** are worked out at of US$ 205,616 represent the incremental operating costs for one year of post-project operation.

Details of cost calculations are provided in Annex-I.

Funding Request

The total funding request to MLF representing eligible incremental costs is for US$ 557,667.

Implementation

Project Monitoring Milestones

MILESTONE/MONTHS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Start-up of project activities	■																	
Submission of project document for signature	■	■																
Project document signature	■	■	■															
Preparation and request for bids			■	■														
Award of contracts				■	■	■												
Equipment delivery and installation					■	■	■	■	■	■	■	■						
Commissioning and trial runs											■	■	■	■	■			
Training and technical assistance														■		■		
Commercial production																■	■	■

Management

The project will be under the overall management and coordination of the Foreign Economic Cooperation Office, Ministry of Environment Protection of China. UNDP is being the implementing agency for the project, which will provide international coordination and technical assistance as needed.

Environmental Impact

The HCFC-141b consumption during 2009 at Zhejiang Kindly Medical Devices Co. Ltd. is 28.72 metric tonnes.

Substance	Quantity	ODP	GWP	CO_2-eq emissions
HCFC-141b	27.82	0.11	713	19,836
KC-6	42.80	0	20	856
Impact		**(3.06)**		**(18,980)**

Based on the above, the successful implementation of this project will result an annual reduction of minimum 3.06 ODP tonnes and annual direct emission reductions of 18,980 tonnes CO_2-eq.

Results

The successful implementation of this project will result in the following:

(a) Sustainable reductions in HCFC consumption in the Solvents sector in China of 3.1 ODP tonnes, contributing to China's compliance with the 2013 and 2015 control targets

(b) Demonstration and availability of an environmentally safe and cost-effective alternative for enabling replication of this technology in similar applications and enterprises in the Medical Cleaning Applications sub-sector in China

ANNEX-III

Incremental Capital Costs

No.	Item/Description	Unit	Qty	Cost (US$)
1. Needle assembly line modifications				
1.1	Local exhaust device	Set	1	11,095
1.2	Hot air dryer	Set	1	12,130
1.3	Conveyor modifications	Set	1	14,053
1.4	Intermediate inspection bench	Set	1	7,396
1.5	Installation and commissioning	Lot	1	7,396
1.6	Electronics adjustment and debugging	Lot	1	8,876
Subtotal				**60,946**
2. Process Adjustments				
2.1	Additional silicification tooling (100 strips)	Set	100	1,479
2.2	Conveyor to transfer workpieces from silicification tooling to dryer	Set	1	7,396
Subtotal				**8,875**
3. Silicification fluid management				
3.1	Closed liquid mixer	Set	1	7,396
3.2	Safety features (alarm, ex-proof electricals)	Set	1	2,219
3.3	Digital rotary viscometer	Set	1	1,997
3.4	Residue processor	Set	1	8,876
Subtotal				**20,488**
4. Silicification tooling line modifications				
4.1	Modification of ultrasonic cleaning line and mechanization	Lot	1	73,964
4.2	Workpiece loading container	Nos	50	6,213
4.3	Solvent recovery system	Lot	1	17,751
4.4	Installation and commissioning	Lot	1	5,178
4.5	Electronics adjustment and debugging	Lot	1	3,698
Subtotal				**106,805**
5. Performance evaluation				
5.1	Evaluation of form	Lot	1	148
5.2	Puncture testing	Lot	1	2,959
5.3	Biocompatibility testing	Lot	1	2,975
5.4	Drug compatibility testing (statutory authorities)	Lot	1	29,586
5.5	Silicification form evaluation	Lot	1	148
5.6	Silicification durability evaluation	Lot	1	3,107
Subtotal				**38,923**
6. Other				
6.1	Design and technical expert fees, technical assistance	Lot	1	34,023
6.2	Process trials	Lot	1	10,000
6.3	Process and safety training	Lot	1	9,986
6.4	Documentation, reporting and information dissemination (UNDP)	Lot	1	8,000
6.5	Project management(FECO)	Lot	1	27,883
6.6	External monitoring and experts verification(FECO)			11,122
Subtotal				**101,014**
Total				**337,051**
Contingencies				15,000
Grand total				**352,051**

ANNEX-IV

Incremental Operating Costs

Item/Description	Unit	Before conversion			After conversion			Difference (US$)
		Unit price (US$)	Qty	Total (US$)	Unit price (US$)	Qty	Total (US$)	
Needle Assembly								
Silicification fluid	kg	2.66	9,200	24,472	6.21	9,200	57,132	32,660
Needles wastage	million pc	0.010355	0	0	0.010355	2.89	29,926	29,926
Subtotal								***62,586***
Silicification Tooling Cleaning Line								
Silicification fluid	kg	2.66	33,600	89,376	6.21	33,600	208,656	119,280
Sub-total								***119,280***
Production Line								
Increased electrical load due to additional equipment	kWh	0.125	0	0	0.125	190,000	23,750	23,750
Sub-total								***23,750***
Grand Total								**205,616**