

PD-ABG-711

ISN 84278

AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D.C.

**AMENDMENT NO. 1
to the
PROJECT MEMORANDUM**

**NEW INDEPENDENT STATES
HEALTH CARE IMPROVEMENT
(110-0004)**

APPROVED: July 28, 1993



JUL 28 1993

U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

ACTION MEMORANDUM FOR THE DIRECTOR, NIS TASK FORCE

THRU: Barbara Turner, NIS/TF *BT*
FROM: Carlos Pascual, NIS/TF/PACD *CP*
SUBJECT: Authorization Amendment No. 1 for the Health Care Improvement Project (110-0004)

PROBLEM:

Your approval is needed to increase the authorized life of project (LOP) funding of the Health Care Improvement Project from \$40 million to \$100 million and to extend the Project Assistance Completion Date (PACD) to December 31, 1997. This will support increased obligations over the next four years of \$55 million for major health care finance and service delivery reforms in the NIS; up to \$4.5 million of start-up funding for women's health/family planning, primarily in the Central Asian Republics; and up to \$500,000 for support of limited environmental health activities.

BACKGROUND:

In March, 1992 A.I.D. authorized the Health Care Improvement Project at a level of \$40 million over four years from the date of first obligation (5/15/92). The project was designed to respond to three immediate problems identified by the NIS Medical Assistance Working Group, which were:

1. Declining quality of health care and an anticipated increase in death rates from preventable and treatable diseases;
2. Collapse of the pharmaceutical and medical supply industry and a resulting inability to manufacture medicines and medical supplies; and
3. Lack of funding, and a financing system devoid of any incentives for efficiency and cost control.

In response to these three problems, the A.I.D. Europe Bureau developed a project for the NIS designed to: transfer modern U.S. medical knowledge and technology; help reestablish the production of pharmaceuticals, vaccines and medical supplies; support efforts to expand U.S. trade and investment; and reform health care systems in the NIS. The project had three components,

including: (1) the transfer of medical knowledge and technology through hospital-to-hospital partnerships; (2) the reestablishment of productive capacity for producing and delivering medicines, vaccines and medical supplies, as well as assessments of production facilities by industry audit teams, and (3) the promotion of health trade and investment, and health delivery alternatives (called Expanding Health Trade, Investment and Alternatives).

In February of 1993, a Congressional Notification (CN) was sent to the Hill informing Congress that the project was being increased from \$40 million to \$45 million to address the special needs of women and children, particularly related to women's reproductive health in Central Asia. Because commencement of women's health activities was delayed until now, a project authorization amendment reflecting the additional scope outlined in the CN was not previously done. Through this authorization amendment, such activities will become Component 4 of the project, and will include preliminary activities to initiate and accelerate technical assistance to respond to women's health and family planning needs, primarily in the Central Asian Republics. These limited activities are preparatory to the design and funding of a longer-term NIS-wide Women's Health and Family Planning Initiative now being designed.

Purpose of Amendment:

The major purpose of this authorization amendment is to expand and more clearly define Component #3 of the project, Expanded Health Trade, Investment and Alternatives, in support of a major health care finance and service delivery reform initiative at a level of \$55 million over the next three years. In the original Project Memorandum the budget for this component was estimated to be \$10 million. This authorization amendment increases it to \$65 million, and means that funding for Component #3 will now comprise about two-thirds of the total project.

Another purpose of this amendment is to provide up to \$4.5 million to support initial funding to accelerate technical assistance for improving women's health through the expansion of family planning services, primarily in the Central Asian Republics. This component, referred to as Component #4 of the Health Care Improvement Project, will focus on increasing access to family planning through service expansion, and the introduction of modern contraceptives through technical assistance, training and communications activities. It will also support some limited analytical and design efforts in the NIS, to facilitate strategy development for an NIS-wide Women's Health Initiative, with a major focus on family planning and other selected interventions to improve women's reproductive health status and conditions. It is intended to serve as a bridging mechanism to address urgent women's health and family planning

needs in the Central Asian Republics while a more comprehensive program is developed.

The third purpose of this amendment is to provide up to \$500,000 to support limited environmental health initiatives. This will become Component 5 of the project and may be expanded at a later date based on Washington and field priorities.

Programming to Date:

Of the \$10 million originally planned for Health Trade, Investment and Alternatives (Component 3), to date \$3.5 million has been obligated through Inter-Agency Agreements (IAAs), the bulk of which has gone to the Overseas Private Investment Corporation (OPIC), the Department of Commerce (DOC), and the Trade and Development Agency (TDA). OPIC funding supported a fifty-company investment mission to Russia in June 1992, a two-day business seminar on investment opportunities in Central Asia and the Caucuses, and feasibility studies for U.S. businesses contemplating NIS investments. The IAA with Commerce supported a seminar in June 1992 on U.S. government programs to assist businesses in the NIS health sector, a health industries development mission to Russia and Tatarstan in October 1992, and health industry seminars and a roundtable on marketing used or remanufactured health equipment. TDA funding has supported larger technical and economic feasibility studies aimed at promoting U.S. exports. The project will continue to support the above inter-agency agreements through FY 94 as planned, possibly focussing them more directly on critical medicines and supplies. Expansion beyond FY 94 will be considered based on an evaluation of the program's effectiveness slated for early 1994.

To date there has been no programming in women's health/family.. planning or environmental health through this project, since these activities are not yet authorized. Any such activities in the NIS which occurred have been funded by R&D.

**Part I: Health Care Finance and Service Delivery Reform
Initiative: Expansion of Component 3:**

Rationale: Even before the dissolution of the Soviet Union, the health status of the NIS populations was poor relative to OECD countries, and underfunding of health care and the excessive expansion of staff and facilities have contributed to a low quality of care, low staff motivation, commodity shortages and insufficient maintenance of equipment and facilities. Worse yet, this situation is in serious danger of declining further as a result of the extreme fiscal crises facing all NIS republics, disrupted health commodity supply lines, and declining incomes and nutritional standards.

In their efforts to avoid economic chaos and achieve

macroeconomic stability, NIS governments (particularly Russia's) have been forced to decentralize some of the responsibility and authority for health care systems and other social safety net functions to local and regional levels. All of the new republics are now struggling with new, more market-oriented ways of meeting strident public demands for health care services with limited public resources. Privatization of health finance and delivery systems is in its infancy across the NIS, with many republics lacking the policy, legal and regulatory structures critical to the emergence of effective private systems. These structures are unlikely to evolve until governments, medical practitioners, entrepreneurs and the population as a whole accept that market-oriented systems can create efficiencies which will allow more effective health coverage, even with existing limited resources.

Prior to 1987 when the first health sector reforms were introduced, the entire Soviet system was public; private practice did not exist. There was no distinction between financing and provision, since all facilities were publicly owned and all medical care personnel were employed by the state. The Union Ministry of Health determined the budget and relied heavily on quantitative production norms such as numbers of facilities, manpower, and hospital bed days of care. Equipment was allocated to the republic health ministries and then to regional and local levels.

Starting in 1987, the management of the health system was decentralized to the republic level with the republics having the primary responsibility for managing both the financing and delivery of care. Nevertheless, deviations from the Union MOH spending plans were relatively small.

In late 1991 with the dissolution of the Soviet Union, real power and control devolved to the republic level concomitant with receipt of taxing authority. With the exception of Russia, all budgets and decision making authority for the health sector in the NIS remain largely centralized at the national level. In Russia, while responsibility for overall policy and the legal and regulatory structure rest at the national level, both the financing of care and its provision rest at the regional level with some 95 percent of all funding going directly to regions. National level activities center on the traditional public health, medical education and capital allocation roles, as well as the equalization of health capacity across regions.

Most NIS governments have begun the arduous process of health finance and service delivery reform, starting with the passing of laws that define the principles, legal rights and organization of medical services along more market-oriented lines, and legislation that moves away from global budgeting to more efficient systems of health finance such as health insurance. Some republics are further along in this legislative process than

others. The privatization of State enterprises, now accelerating in Russia and on the drawing board in other countries will create a special set of health financing issues. A high percentage of NIS populations have historically depended on workplace-based health clinics for primary care. To the extent that these facilities are downsized or eliminated in the privatization process, there will be increased demand for alternative sources of health care, and stimulus for the creation of new, increasingly private health care systems.

The task confronting NIS officials today involves maintaining access to affordable health care, while making its delivery more effective and efficient through reforming health finance and delivery systems. Although the passing of legislation to reform health systems is a critical step in the right direction, reforms have been hampered by a number of constraints which this project plans to address, including:

- . Few in government and the private sector understand the basic concepts of insurance;
- . Existing legislation and policies affecting reform are often ambiguous or contradictory;
- . Systems for determining costs, payments, and premiums are practically nonexistent;
- . Third party administrators such as private insurance companies are very new and lack business skills and experience;
- . Redundant public health facilities continue to receive subsidies;
- . Private health care providers that would provide true competition to the public sector are nascent; and
- . The general quality of care provided in the health system is poor.

Design and Implementation: Component 3 funding will now largely support the Health Care Finance and Service Delivery Reform Program, aimed at developing model systems to restructure health care financing and management in a manner that reduces costs and improves the quality of care. This is budgeted at approximately \$55 million over the next three years.

To this end, NIS/DIHR is soliciting bids from U.S. firms/organizations to develop a comprehensive reform plan in up to seven sites/areas of the NIS which will make health care delivery more cost effective, improve quality of care, and increase access to care and provider choice through market-

oriented reforms of the health finance and service delivery systems. DIHHR will further request that the contractor(s) work closely with each field mission to better define the nature of the health financing and service delivery problems in each country and to promote synergies across related project activities, including intergovernmental fiscal reform and local government finance; and examine the impact of privatization of state enterprises on the provision of health services at the regional level, particularly in regions where the populations are heavily reliant upon state enterprises for health care. State enterprise health care systems will be considered as possible targets for project assistance, assuming it makes sense to do so.

By the end of the project, the Health Care Finance and Service Delivery Reform Program should have demonstrated the value of a number of reforms such as: elimination of public monopolies of health care financing and service delivery; improved management (including financial management) by service delivery providers; increased consumer responsibility for health care; increased budgetary and operational authority by service delivery managers over their programs; increased share of insurers and service delivery providers employed by the private sector; reduced use of the more costly, tertiary facilities (hospitals) for primary care services and increased use of entry-level facilities and services; competition among insurers and service delivery providers for clients; and increased user satisfaction with availability and price of services.

Part II: Women's Health/Family Planning (Component 4):

Rationale: In the NIS, limited access to modern family planning methods and resulting reliance on abortion for fertility control have severely compromised women's health. Moreover, while the health care system provides universal coverage, medical procedures and protocols related to family planning, maternal and newborn care, and breastfeeding are frequently outdated and inappropriate. Health professionals, many of whom are highly trained, have been isolated from many of the most important health developments of the twentieth century.

Although maternal mortality has declined in the last decade, in Russia, the 1989 rate of 49 deaths per 100,000 live births was seven times greater than the ratio in the United States. Toxemia is cited as the most common cause of maternal mortality, followed by infections, hemorrhage and hepatitis. Other factors which may contribute to women's poor health status and maternal mortality are nutritional anemia, employment requiring heavy labor and exposure to environmental pollutants, and high fertility with short birth intervals.

Use of modern contraceptives remains low throughout the NIS, due to: limited understanding of the health benefits of family

planning; insufficient information and education among health providers; a cultural bias against contraceptives, particularly by men; a chronic shortage of modern, high quality contraceptives; lack of information among the general public about alternatives to abortion; and concerns about the perceived side-effects of contraceptives, especially hormonal contraception. Resulting from the absence of an up-to-date body of scientific and medical information, many outdated and potentially harmful practices persist.

Design and Implementation: As stated above, DIHHR is now beginning design of an NIS-wide in-depth women's health and family planning program. In the interim, DIHHR plans to add funds to several R&D Bureau contracts with FY 1993 funds to address some of the more pressing health problems, in order to accelerate technical assistance to the Central Asian Republics, where infant and maternal health status indicators are the worst in the NIS. Up to \$4.5 million in buy-ins/add-ons are planned for the following R&D projects:

Strategic Planning

Options for Population Policy (OPTIONS II) -- \$300,000

Training

Johns Hopkins Program for International Education in
Obstetrics & Gynecology (JHPIEGO) -- \$580,000

Association for Voluntary Surgical Contraception (AVSC)
-- \$950,000

Information, Education and Communication (IEC)

Johns Hopkins Population Communication Services (JHU/PCS)
-- \$700,000

Demographic and Health Surveys (DHS) -- \$507,390

Technical Support

IQCs and other design and implementation mechanisms
-- \$500,000

**Part III: Environmental Health: Rationale and
Design/Implementation**

Historically, the Soviet Union did not consider the health impacts of manufacturing, pesticide use and other production activities. It is only recently that the governments of the NIS have begun to examine an association between environmental pollutants and the high levels of cancer, birth defects, childhood respiratory illnesses and lead contamination. Such problems are particularly acute in Ukraine, Byelarus and Russia as a result of Chernobyl; in the Central Asian nations bordering the Aral Sea; in the Souther Ural Mountains of Russia; and in other more localized areas throughout the NIS.

Despite growing fears, the countries of the NIS have little reliable data to measure the problem; lack an industrial and agricultural sector that's knowledgeable about the impacts of pollutants and pesticides on both humans and the environment; have no regulatory agencies to enforce public and private sector producers to eliminate or minimize environmental contamination; and have a scarcity of scientific and epidemiological knowledge needed to measure the impact of environmental toxins upon health. This means there is no way to identify and prevent new sources of contamination -- a critical and timely issue during this transitional period when industry throughout the NIS is becoming increasingly privatized and decentralized.

Because of the U.S.' predominant expertise in identifying and addressing environmentally caused illnesses, the Task Force has been considering funding some pilot activities in environmental health. These are tentatively budgeted up to \$500,000 and could be funded through buy-ins to R&D's new Environmental Health Project. Activities being considered for assistance include a pilot project for improving the quality of drinking water around the Aral Sea, epidemiological surveys and training for scientists and health professionals; and professional exchanges for relevant public officials, health professionals, and industrial and agricultural leaders involved in environmental health issues.

CONGRESSIONAL NOTIFICATIONS:

Two Congressional Notifications were submitted to Congress related to this authorization request. The first was submitted on February 5, 1993, informing Congress of a planned increase in the authorization level from \$40 to \$45 million to support a Women and Children's Health Program. As stated earlier, the project authorization was not subsequently amended.

The second Congressional Notification was sent to Congress on June 18, 1993; expired on July 3, 1993. It informs Congress of a planned increase in the authorization level from \$45 to \$100 million to support the Health Care Financing and Service Delivery Reform Component, and to extend the project completion date from May 15, 1996 to December 31, 1997. The most recent CN also restates our intention to begin a women's health/family planning initiative and informs Congress that we also intend to support selected environmental health activities.

AUTHORIZATIONS:

The Appropriations Act bars obligations of more than 50% aid (other than humanitarian assistance) to Russia until the President certifies substantial progress toward establishing a timetable for withdrawal of CIS and Russian armed forces from the Baltics. The President so certified to Congress on June 1, 1993.

Section 498A (a) of the Foreign Assistance Act of 1961, as amended, sets forth a number of matters that are to be taken into account in providing assistance to NIS countries, such as progress toward democracy and economic reform, human rights, peaceful resolution of ethnic disputes and restraining arms transfers. Section 498A (b) prohibits aid to any NIS country that violates any of a number of restrictions relating to matters such as human rights, arms control, nuclear proliferation, and with respect to Russia, withdrawal from the Baltics.

The Secretary of State as Coordinator has reviewed memoranda dealing with these statutes for Armenia, Georgia, Kazakhstan, Russia, and Ukraine and decided to proceed with assistance to these countries. State advises that memoranda for the other countries are in process and we are in this way satisfying the 498A (a) criteria. The section 581 criteria (significant steps toward human rights implementation; political pluralism based on democratic principles and the rule of law; and economic reform, based on market principles and private property) have in fact been important considerations taken into account throughout the process of providing assistance to the NIS. State and A.I.D. agree that Sections 581 and 489A (a) do not preclude providing assistance to these countries at this time.

Section 599 of the FY 1993 Appropriations Act sets forth restrictions on assistance which could have an adverse impact on U.S. employment or on workers' rights in the recipient countries. GC and PAC have developed standard clauses which will be incorporated in PIO/Ts for all grants and contracts and in Interagency Agreements to ensure compliance with this section.

The Secretary of State signed a Section 620(f) determination to permit assistance for the states of the former Soviet Union on September 10, 1991. You have the authority to authorize the project pursuant to Interim Reorganization Delegation of Authority No. 10, dated March 30, 1992. The Congressional Notification for the Project expired on July 3, 1993. There are no outstanding waivers or policy concerns.

RECOMMENDATION:

That you, as Director of the NIS Task Force: (1) approve this action memorandum and the attached Project Authorization Amendment No. 1, thereby authorizing the amendment to the Health Care Improvement Project (110-0004), and (2) review and sign the attached Initial Environmental Examination (Tab D) for the project, thereby indicating your approval of its findings and implications for project implementation.

Approved: *J. Crandall*
 Disapproved: _____
 Date: 7/26/93

Attachments:

- a) Project Authorization Amendment
- b) Revised Project Budget
- c) Detailed Health Care Financing Budget
- d) Initial Environmental Examination

Drafted: SMorawetz; U:\smorawet\docs\nis\health\auth004
 U:\opscis\docs\healthauth.004

Clearances:

GC/NIS:BBryant	(draft)	Date	6/30/93
NIS/TF/OD:BTurner	<i>BT</i>	Date	7/26/93
NIS/TF/OD:LCrandall		Date	
NIS/TF/PAC:CPascual		Date	
NIS/TF/CONTR:JWinn	(draft)	Date	7/1/93
NIS/TF/EET:DLong	(draft)	Date	6/29/93
NIS/TF/DIHR:GDonnelly	(draft)	Date	6/24/93
NIS/TF/DIHR:MARiegelman	(draft)	Date	6/21/93
NIS/TF/DIHR:PBryan	(draft)	Date	6/15/93
State/NIS:HBomburger	(draft)	Date	7/9/93
State/EUR/ISCA:NCook	(draft)	Date	7/12/93

**HEALTH CARE FINANCE AND DELIVERY REFORM
DRAFT BUDGET (\$000)**

ELEMENT (Inflation = 5%/year)	PRSN YRS		3 YEAR			
	PER 2 SITES	\$/UNIT	YEAR 1	YEAR 2	YEAR 3 SUB-TOTAL	
A. RUSSIA (2 sites + regional/national)_						
TECHNICAL ASSISTANCE						
1. US Long-Term						
Finance Advisor	5.00	325	650	683	358	1,690
Management Advisor	5.00	325	650	683	358	1,690
Quality Assurance Advisor	3.00	325	325	341	358	1,024
Training Advisor	3.00	250	250	263	275	788
Innovation & Policy Advisor	3.00	325	325	341	358	1,024
Field Director	0.00	325	0	0	0	0
Fiscal/Admin.	3.00	250	250	263	275	788
Information, Monitoring & Coordination	1.00	250	250	0	0	250
Russia - Regional Services	2.00	325	325	341	0	666
Total US LT	25.00		3,025	2,914	1,980	7,919
2. Russian Long-Term						
Finance Advisor	6.00	21	42	44	46	132
Management Advisor	6.00	21	42	44	46	132
Quality Assurance Advisor	6.00	21	42	44	46	132
Project Mgt. Spc.	21.00	18	123	129	135	388
Administrative Support	18.00	11	63	66	68	198
Training Advisor	3.00	18	18	18	19	55
Innovation & Policy Advisor	3.00	21	21	22	23	66
Field Director	3.00	21	21	22	23	66
Fiscal/ Admin.	3.00	18	18	18	19	55
Russia - Regional Services	3.00	21	21	22	23	66
Grants Manager	3.00	18	18	18	19	55
Total Russian LT	72.00		410	430	450	1,290
3. US Short-Term (\$22,000/wth X 12m/yr)	113.00	264	1,056	1,386	1,162	3,604
4. Russian Short-Term	30.00	1	12	13	13	38
SUB-TOTAL TA FOR 2 SITES IN RUSSIA	240.00	265	4,503	4,742	3,605	12,850
5. Small Grants Fund		400	800	840	890	2,520
6. Other Direct Costs (per year for 2 sites)						
Training Costs (materials + other costs in NIS + US training)		200	400	420	440	1,280
Communications & Dissemination		100	200	210	220	630
Rent & Utilities		100	200	210	220	630
Equipment & Furnishings		75	150	158	0	308
Office Supplies		20	40	42	44	126
Miscellaneous		50	50	53	55	158
Sub-Total Other Direct Russia			1,040	1,082	979	3,111
SUB-TOTAL 2-SITES RUSSIA			6,343	6,674	5,484	18,481

B. OTHER SITES (cost of 1 site in Russia X 60%)			1,803	2,002	1,639	5,544
SUB-TOTAL OTHER FIVE SITES			9,514	10,011	8,196	27,722
C. ALMATY SUPPLEMENT		100	100	105	110	315
D. PROJECT/NIS - WIDE OFFICE IN U.S.						
Project Manager	3.00	80	80	84	88	262
Coordinator/Technician	3.00	45	45	47	50	142
Coordinator/Technician	3.00	45	45	47	50	142
Training Coordinator	3.00	45	45	47	50	142
Administration & Support	3.00	35	35	37	39	110
Translation and Interpretation	3.00	20	20	21	22	63
Subtotal Salaries			270	284	297	851
Benefits @ 30%			81	85	89	255
Overhead @ 75%			203	213	223	638
SUB-TOTAL	18.00		554	581	609	1,744
SUB-TOTAL SITE & NIS-WIDE ACTIVITIES			16,510	17,372	14,379	48,261
G & A (10 % of total costs less support funds)			1,571	1,653	1,350	4,574
FEE (7 % of total costs less support funds)			764	804	574	2,143
GRAND TOTAL			18,844	19,830	16,304	64,978

NOTE: Allocation to Russia is approximately \$33 million for three years, assuming the first two sites at \$18.5 mil., the second two sites at \$11 mil., one-third of the costs of the U.S. office (.6 mil.) and 40% of the G&A + fee (\$2.7 mil.).

INITIAL ENVIRONMENTAL EXAMINATION

- A. PROGRAM COUNTRY: New Independent States
- B. ACTIVITY: Amendment: Health Care Improvement Project 110-0004
- C. FUNDING: \$100 million
- D. FUNDING PERIOD: FY 1992 - FY 1998
- E. STATEMENT PREPARED BY: Paula Bryan, NIS/TF/DIHHR
- F. RECOMMENDED ENVIRONMENTAL ACTION: Categorical exclusion under AID Regulation 22 CFR 216, Environmental Procedures, Sections 216.2(c)(1)(i) and 216.2(c)(2)(i) and 216.2(c)(2)(viii). Terms and conditions of the original IEE (copy attached) for the initial \$40 million remain unchanged, except for an extension of the time period from FY 94 to FY 98.
- G. DECISION OF NIS ENVIRONMENTAL OFFICER: *A.O.T.*
Approved

Disapproved

Date
- H. DECISION OF DIRECTOR, NIS TASK FORCE *J. W. Beck*
Approved

Disapproved

7/25/98
Date

**EXAMINATION OF THE NATURE, SCOPE AND MAGNITUDE
OF THE ENVIRONMENTAL IMPACT**

A. DESCRIPTION OF THE PROGRAM:

This IEE covers the entire Health Care Improvement Project, though it focuses primarily on activities that will be added through Authorization Amendment 1. Additions include: Health Finance and Service Delivery Reform Program (an addition to the exiting component 3 -- Expanding Health Trade, Investment and Alternatives); start-up activities for women's health/family planning (to become component 4); and start-up activities for a small environmental health program (to become component 5). The authorization amendment includes no changes to the Health Care Improvement Project's first two components: Medical Partnerships (component 1) and Reestablishing Productive Capacity (component 2).

The principal element of the amendment is the Health Finance and Service Delivery Reform component, which provides assistance to reform selected health care finance and service delivery systems throughout the New Independent States. It focuses on methods to enhance private sector participation in the production of health care inputs, and the delivery and finance of health care services. The component will provide technical assistance and training to individuals, health care facilities and educational institutions. A small amount of commodities and equipment will be purchased. There is no impact on the environment as far as AID-managed activities are concerned. This project is not intended to support construction or pharmaceutical manufacturing activities. A further environmental review will be undertaken of such activities if they are pursued.

B. RECOMMENDED ENVIRONMENTAL ACTION:

Because the project provides only education, technical assistance and training, a categorical exclusion from AID's Initial Environmental Examination, Environmental Assessment and Environmental Impact Summary requirements is proposed. This proposal is in accordance with AID Environmental Procedures 22 CFR Section 216.2(c)(1)(i), which generally provides for categorical exclusion in situations where the project has no effect on the natural or physical environment. Specifically, this activity is categorically excluded under Section 216.2(c)(2)(i) for education, technical assistance and training, and Section 216.2(c)(2)(viii) for nutrition, health care, and population programs.

U:\opscis\docs\iee.0004

INITIAL ENVIRONMENTAL EXAMINATION

(A) PROGRAM COUNTRY: New Independent States
 (B) ACTIVITY: Health Care Improvement Project No. 110-0004
 (C) FUNDING: \$40.0 million
 (D) PERIOD OF FUNDING: FY 1992 - FY 1994
 (E) STATEMENT PREPARED BY: Linda Lou Kelley, EUR/DR/HR

(F) RECOMMENDED ENVIRONMENTAL ACTION:
 (1) Categorical Exclusion for technical assistance and training in the Medical Partnerships and Expanding Health Trade, Investment, and Alternatives components and
 (2) deferral of determination for the Reestablishing Productive Capacity component under A.I.D. Regulation 22 CFR 216, Environmental Procedures, Sections 216.2 (c)(1)(i) and 216.2(c)(2)(viii).

(G) DECISION OF DEPUTY ASSISTANT ADMINISTRATOR, EUR:

Dwight Morris
 Approved

Disapproved
4/17/92
 Date

(H) DECISION OF EUR ENVIRONMENTAL COORDINATOR:

Ronald Greenberg
 Approved

Disapproved
4/17/92
 Date

EXAMINATION OF THE NATURE, SCOPE AND MAGNITUDE
OF THE ENVIRONMENTAL IMPACT OF
THE HEALTH CARE IMPROVEMENT PROJECT, NO. 110-0004

A. DESCRIPTION OF THE PROGRAM:

The purpose of the project is to improve health care in the former Soviet Union by transferring modern American medical knowledge and technology, helping to reestablish the production of pharmaceuticals, vaccines, and medical supplies, and supporting efforts to reform selected health care systems in the New Independent States (NIS). This purpose will be accomplished through the provision of technical assistance, training, limited diagnostic and medical treatment equipment, commodities for vaccine or pharmaceutical production, and pre-investment work such as feasibility studies.

Pharmaceutical production has declined by 50% or more in the New Independent States, with the result that widespread shortages of life-saving pharmaceuticals and vaccines are considered to be imminent. Under this project, teams will conduct production audits of existing manufacturing facilities to determine where and how production can be restored to meet the needs for key products. These teams will include individuals with corporate experience in environmental health and safety and environmental engineering. The production audits will include an environmental review of the existing facilities and processes, including health and safety procedures. Findings and recommendations concerning the environmental setting and management, personnel health and safety, and process safety will be included in the report on these facilities.

Based on these production audits, assistance will be provided to selected facilities in order to restore production of key pharmaceuticals and vaccines. This may entail technical assistance, limited equipment, or supplies required for production. At this time, it appears that supplies will be the primary form of support needed to restore production. Procurement of supplies (such as culture medium or chemicals required in production) will be carried out by U.S. companies which produce the target pharmaceuticals or vaccines. The materials supplied will be accompanied from port to production site, and storage will be supervised. Four months after materials receipt, all plants will be visited by a technical team to ensure that materials are being stored and used effectively and to provide any additional technical guidance needed.

In addition, while procurement of commodities is being arranged, the directors of the production units will be brought to the U.S. to observe good manufacturing practices (GMP) at the manufacturing operations of companies producing comparable vaccines or pharmaceuticals, and to visit relevant units of the Food and Drug Administration. These organizations will provide

seminars, tours, and detailed information to expand the appreciation of their NIS colleagues for infrastructural and organizational implications of GMP and environmental safeguards. This will promote understanding and enable discussion of the amount of change and renovation which is ultimately required for production, management, and regulatory processes to meet modern standards of efficiency and safety.

In addition to the short-term efforts to identify "quick fixes" aimed at restoring production on an emergency basis, the project will carry out medium term studies and other activities aimed at providing a bridge to the kinds of investments which will be required to construct new production facilities. Preliminary visits to civilian production facilities in the New Independent States indicate that most facilities are old and outmoded. Many are located within city limits, in close proximity to residential areas. Major investments (on the order of \$40-100 million) will be required to replace and relocate these plants. The project will support detailed feasibility studies to enable the governments involved, corporate investors, commercial banks, and the World Bank or its affiliates to make investment decisions. The replacement of plants which are badly located and outmoded will have positive impacts on the present high levels of environmental pollution and degradation in the NIS.

The studies will also provide a concrete mechanism for embarking upon discussions with governments and local producers regarding privatization of production facilities. Privatization will not only reward efficiency, but will also provide the separation between production and regulation (now often under the same government Ministry) required for effective regulation.

B. RECOMMENDED ENVIRONMENTAL ACTIONS:

Most project resources will be used to finance technical assistance, training, and studies, for which a categorical exclusion from A.I.D.'s Initial Environmental Examination requirements is proposed. This is in accordance with A.I.D. Environmental Procedures 22 CFR Part 216(c)(1)(i) which generally provides for a categorical exclusion in situations where the action does not have a direct effect on the natural or physical environment. Specifically, components one and two, Medical Partnerships and Expanding Health Trade, Investment, and Alternatives, respectively, are categorically excluded under Sections 216.(c)(2)(viii) for the programs which involve the delivery of health care services.

Activities under the Reestablishing Productive Capacity component, such as purchase of pharmaceutical and vaccine supplies and installation of new production equipment, which is planned for specific plants, could have negative environmental effects. The supplies which may be purchased with project funds may include chemicals which could be hazardous to human health if

not properly stored, utilized and disposed of. Equipment provided to rejuvenate plant production may indirectly prove hazardous to human health if not properly operated and maintained, once installed. With regard to planned assistance to vaccine production facilities, potential environmental hazards include improper containment and disposal of diseased test animals, as well as improper clean-up and disposal of contaminated waste from animal farms where animals have been tested.

Further, assistance that results in improving production, without addressing waste minimization, pollution prevention and pollution control, may indirectly contribute to environmental effects, or appear to suggest that environmental pollution was an acceptable action as part of western production systems.

Since specific pharmaceutical and vaccine plants have not yet been selected for receipt of supplies and equipment, specific potential environmental effects cannot be determined at this time. Therefore, a deferral of a negative or positive environmental determination is recommended for this component of the program. Once specific plants have been assessed and selected, an environmental determination covering the provision of A.I.D. assistance will be made.

In order to ensure that environmental considerations are integrated into the project, the procedures outlined below will be followed. The Project Officer will be responsible for ensuring that activities are undertaken in a timely manner and documents are submitted to the Bureau Environment Coordinator for action.

1. The Bureau Environmental Coordinator will review the scopes of work and consultant CVs for the production audits to ensure that environmental issues will be thoroughly investigated and that qualified environmental consultants are selected for the team. Production audits will contain a brief assessment of potential environmental hazards; energy, water and chemical use; current environmental practices; and actions recommended to mitigate potential dangers.
2. The Bureau Environmental Coordinator will review the reports prepared by the production audit teams. These reports generally will serve as final environmental reviews. Based on his/her review of these reports, the Bureau Environmental Coordinator will determine whether a more detailed environmental assessment is warranted.
3. The Bureau Environmental Coordinator will review plant selection criteria developed by the Project Officer to ensure that potential environmental concerns are incorporated.

13

4. In the event that several environmental assessments are required, the Project Officer and Bureau Environmental Coordinator will consider establishing or using a separate contractor to conduct the analysis.

5. If a more detailed environmental assessment is required, the Bureau Environmental Coordinator will review, and when complete, approve, scopes of work, the selection of contractors to perform the work, final reports, and mitigation plans.