

## RADIATION STERILIZATION OF HEALTH CARE PRODUCTS (VIE/8/010) F5

### MODEL PROJECT

#### CORE FINANCING

YEAR	Experts		Group Activity	Equipment	Fellowships		Scientific Visits		Group Training	Sub-Contracts	Misc. Comp.	TOTAL
	m/d	US \$	US \$	US \$	m/d	US \$	m/d	US \$	US \$	US \$	US \$	US \$
1999	1/12	20,580	0	230,000	0/0	0	0/15	5,400	0	0	0	255,980
2000	0/21	10,815	0	20,000	3/0	10,800	0/0	0	0	0	0	41,615
2001	0/21	11,340	0	20,000	3/0	11,250	0/0	0	0	0	0	42,590

First Year Approved: 1995

Total expenditure to 30 September 1998:

\$207,114 (TCF)

**OBJECTIVES:** To establish an irradiation centre for sterilizing medical products and pharmaceuticals in order to establish a commercially viable industry.

**BACKGROUND:** The Vietnamese health care industry is at an early stage, and the lack of sterilization capability is a major constraint to its further development. An existing small ethylene oxide sterilization unit is totally inadequate for industrial production. An industrial radiation sterilization facility would, as in many developed countries, provide incentive and opportunity for the growth of this industry, and improve health care standards. The immediate aim of this project is to establish a service irradiation centre for sterilizing medical products such as disposables, pharmaceuticals and packing for pharmaceuticals, which will provide sterilization services to a number of companies in Ho Chi Minh (HCM) City area and beyond. Work in radiation technology has been carried out at the Nuclear Research Institute (NRI), in Dalat. The NRI operates a small Co-60 source, adequate for research, but not for commercial application (although it services a human tissue bank). A gamma irradiator for food products has been installed in Hanoi, but is too far from existing factories (mainly in the HCM City area) and is unsuitable for commercial sterilization. Sufficient trained personnel are available to execute the project and there is an informal agreement with potential end users which will be formalized in the near future to ensure utilization of the facility.

**PROJECT PLAN:** The gamma irradiation facility is going into operation for radiation sterilization services of medical and other health care products early in 1999, according to the following schedule: In July-August 1998, the construction of irradiation room, storage pool, warehouse, electric supply and water supply system was completed. From August to November 1998, the electromechanical equipment for the gamma facility is being received and installed. Early 1999, commissioning of the facility, including loading the Co-60 sources, will start. The selection

and testing of radiation resistant polymers for making medical devices has been evaluated, especially for polypropylene (PP) and polyvinyl chloride (PVC) and tested on a laboratory scale; the final products are under evaluation in accordance with ASTM standards. It is essential to ensure appropriate hygienic conditions for products which are going to be radiation sterilized. Appropriate measures need to be taken at the medical rubber glove factory, HCM City; at the Hungarian-Vietnamese joint venture, HCM City (both producing surgical gloves); and at the medical device factory in Longan province (producing disposable plastic syringes). The demand for radiation sterilization of medical products in HCM City is estimated at 6,000 m<sup>3</sup>/year, including 550 m<sup>3</sup>/year surgical gloves, 450 m<sup>3</sup>/y syringes, 350 m<sup>3</sup>/y intravenous sets, 500 m<sup>3</sup>/y surgical sutures, bandages and tampons, 2,000 m<sup>3</sup>/y surgical dressings, 1,000 m<sup>3</sup>/y traditional drugs (dry type) and 150 m<sup>3</sup>/y leather gloves. This shows that the demand in HCM City alone is higher than the planned capacity of the facility in its first year of operation at 200 K Ci Co-60 sources. This is an encouraging factor for considering an increase in source strength during the second year of operation, which will strengthen the impact of this project.

**NATIONAL COMMITMENT:** Viet Nam Atomic Energy Commission has allocated a Government loan of more than US \$1.5 million for the building and the mechanical parts, to be paid from income earned through the facility's operation. The staff are highly committed and well trained.

**AGENCY INPUT:** The Agency has provided the necessary training for performing the necessary QC-QA and will also provide 150-200 KCi Cobalt -60 sources for the first loading.

**PROJECT IMPACT:** The radiation service centre will produce sterilized medical health care products and pharmaceuticals, which will raise the standard of national health care. National manufacturers of single use disposable syringes and gloves will benefit directly from this project. With a population of about 70 million, Viet Nam constitutes a large enough market for economically viable production. The irradiation industry will be developed gradually. It is expected that the facility will be utilized fully at the end of its first year of operation, which will generate the necessary revenue to upgrade the sources and to ensure its continuity.