OPTIONAL FORM NO. 10
MAY 1962 EDITION
GSA FPMR (41 CFR) 101-11.6

UNITED STATES GOVERNMENT

BEST COPY AVAILABLE

Memorandum

PUBLIC HEALTH SERVICE--BSS

TO : Surgeon General
Through: Executive Officer
Public Health Service

DATE: 12/10/65

FROM : Associate Chief for Environmental Health

403469

SUBJECT: Proposed amendment to the Radiological Health appropriations for Fiscal Year 1967

Attached is a summary of justification and study plans in support of an amendment to the Division of Radiological Health Fiscal Year 1967 appropriation to provide support for expanded investigations into the etiology of thyroid tumors. The reports of the Panel of Experts on Thyroid Diseases and the ad hoc statistical committee both establish the need for extensive and intensive studies to clarify the significance of radiation in thyroid tumorigenesis.

The proposed amendment for Fiscal Year 1967 requests a total increase in funds of $1,200,000, of which $800,000 will be allocated to Human Population Studies, $200,000 to supportive Radiobiological investigations, and $200,000 to environmental studies.

Carrying out the expanded program will entail cooperative efforts between elements within the Public Health Service as well as with other Federal and State agencies. We anticipate that the studies will require assistance from the Division of Chronic Diseases, National Institutes of Health; National Office of Vital Statistics; Epidemic Intelligence Service, Communicable Disease Center; several state health departments; and the Atomic Energy Commission, in order to focus on the most significant problems being posed by the preliminary investigations in Fiscal Year 1966. Provision is also allowed for cooperative arrangements with medical centers and laboratories for diagnostic and therapeutic follow-up of children in whom thyroid lesions are detected.

It is requested that this amendment be approved and forwarded to the Department with a recommendation that it be submitted to the Bureau of the Budget. The Division has taken the first step in planning for expansion of our thyroid studies by considering some reallocation

BEST COPY AVAILABLE

Buy U.S. Savings Bonds Regularly on the Payroll Savings Plan

of Fiscal Year 1966 resources to this program in order to have a reasonable planning phase. We are currently devoting $286,000 and 12 positions in this area. We plan to reallocate $100,000 and four positions to our current efforts. The reallocation will be possible due to savings currently being accomplished through more prudent management of expenditures for travel, communications and equipment.

Harry G. Hanson
Assistant Surgeon General

Enclosures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Budget Page	Heading	1967 Original Estimate	1967 Revised Estimate	1967 Increase
	Radiological Health			
	2. Research, training and technical services	$21,907,000	$23,107,000	$1,200,000

Type size: paint 22 pica Case 180. ed underscore Case 210

STANDARD FORM 300
July 1964, Bureau of the Budget
Circular No. A-11, Revised.
300-101

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Radiological Health

Program and Financing (in thousands of dollars)

Identification code 09-20-0331-0-1-651	1967 actual	1967 estimate	1967 estimate
Program by activities:	Original Estimate	Revised Estimate	Increase
1. Grants			
(a) Research	2,571	2,571	----
(b) Training	3,000	3,000	----
(c) State program development.	3,000	3,000	----
2. Research, training and technical services	13,336	14,536	1,200
Total program costs, funded1/.	21,907	23,107	1,200
Change in selected resources2/....	----	----	----
10 Total obligations.....	21,907	23,107	1,200
Financing			
New obligational authority	21,907	23,107	1,200
(Mono cast: 21.5)	(Mono cast: 5)	(Mono cast: 5)	(Mono cast: 4.9)

STANDARD FORM 303
Long form, page 2 of 2
July 1964, Bureau of the Budget
Circular No. A-11, Revised.
303-101

DEPA ENT OF HEALTH, EDUCATION, AND LFARE
PUBLIC HEALTH SERVICE

FINANCING AND EXPENDITURES (In thousands of dollars)

Identification code	1967 actual	1967 estimate	1967 estimate
	Original Estimate	Revised Estimate	Increase
New obligational authority:			
Current authorization:			
40 Appropriation	21,907	23,107	1,200
41 Transferred to (−)			
42 Transferred from			
43 Appropriation (adjusted)	21,907	23,107	1,200
47 Authorization to spend public debt receipts			
49 Contract authorization			
50 Reappropriation			
Permanent authorization:			
60 Appropriation			
67 Authorization to spend public debt receipts			
69 Contract authorization			
Relation of obligations to expenditures:			
10 Total obligations	21,907	23,107	1,200
70 Receipts and other offsets (items 11–17)			..
71 Obligations affecting expenditures	21,907	23,107	1,200
72 Obligated balance, start of year	7,952	7,952	----
73 Obligated balance transferred			
74 Obligated balance, end of year (−)	-8,468	-8,504	-36
77 Adjustments in expired accounts			
90 Expenditures	21,391	22,555	1,164

Use with Form 303 where 301 is not adequate

(Mono cast: 5) (Mono cast: 5) (Mono cast: 4.9)

Typesized point 22 picas Case 180. ed underscore Case 210

STANDARD FORM 300
July 1964, Bureau of the Budget Circular No. A-11, Revised.
300-101

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Radiological Health

Program and Financing (in thousands of dollars)--continued

Identification code 09-20-0331-0-1-651	1967 actual	1967 estimate	1967 estimate
	Original Estimate	Revised Estimate	Increase

1/ Includes capital outlay as follows: Original estimate, $605 thousand; Revised estimate, $780 thousand; Increase, $175 thousand.

2/ Select resources as of June 30 are as follows: Unpaid, undelivered orders Original estimate, $2,642 thousand; Revised estimate $2,678 thousand; Increase $36 thousand.

(Mono cast: 21.5) (Mono cast: 5) (Mono cast: 5) (Mono cast: 4.9)

304A

DEP TMENT OF HEALTH, EDUCATION, ANT ELFARE
PUBLIC HEALTH SERVICE
Radiological Health

OBJECT CLASSIFICATION (in thousands of dollars)

Identification code 09-20-0331-0-1-651	1967 actual	1967 estimate	1967 estimate
Personnel compensation:	Original Estimate	Revised Estimate	Increase
11.1 Permanent positions	5,829	6,008	179
11.3 Positions other than permanent	177	195	18
11.5 Other personnel compensation	40	46	6
Total personnel compensation	6,046	6,249	203
12.0 Personnel benefits	968	1,014	46
13.0 Benefits for former personnel			
21.0 Travel and transportation of persons	532	607	75
22.0 Transportation of things	135	150	15
23.0 Rent, communications, and utilities	650	650	--
24.0 Printing and reproduction	141	146	5
25.1 Other services	446	596	150
25.1 Project contracts	2,495	2,865	370
25.2 Services of other agencies	108	188	80
25.3 Payment to "Bureau of State Services management fund"	520	550	30
25.3 Payment to "National Institutes of Health management fund"	29	29	--
26.0 Supplies and materials	658	709	51
31.0 Equipment	605	780	175
32.0 Lands and structures	2	2	--
41.0 Grants, subsidies, and contributions	8,571	8,571	--
42.0 Insurance claims and indemnities	1	1	--
99.0 Total obligations	21,907	23,107	1,200

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Radiological Health

PERSONNEL SUMMARY

Identification code 09-20-0331-0-1-651	1967 actual	1967 estimate	1967 estimate
	Original Estimate	Revised Estimate	Increase
Total number of permanent positions	808	835	27
Full-time equivalent of other positions	23	26	3
Average number of all employees	777	800	23
Employees in permanent positions, end of year			
Employees in other positions, end of year			
Average GS grade			
Average GS salary			
Average salary of ungraded positions			

Radiological Health

New Positions Requested in Fiscal Year 1967 Amendment

	Grade	Annual Salary
Research, training and technical services		
Commissioned Officers		
Epidemiologist	Director	$ 13,039
Epidemiologist	Senior	8,928
(5) Physicians	Senior	59,640
(1) Pharmacologist	Senior	8,928
Civil Service		
Statistician (Supervisory)	GS-16	19,619
Veterinary Pathologist	GS-14	14,680
Chemist - Organic Analytical	GS-13	12,510
Chemist - Analytical	GS-12	10,619
Engineer-Chemist	GS-11	8,961
(2) Biological Lab. Techns.	GS-7	12,538
(2) Biological Lab. Techns. (Cyt.)	GS-7	12,538
Nurse	GS-7	6,269
Field Assistant	GS-7	6,269
(3) Laboratory Asst.	GS-7	18,807
(2) Secretary-stenographers	GS-6	11,404
(2) Clerks (Statistical)	GS-4	9,282
Animal Caretaker	GS-3	4,149
Total new positions	27	$238,180

The Bureau of the Budget has established a ceiling for the Bureau of Environmental Health on the numbers of positions at GS-14 and above for 1966. It is requested that the Bureau ceiling for these grades be increased by 2 positions to cover the above request for 1 new GS-14 position and 1 new GS-16 position. High level scientific and management competence will be vital to the successful implementation of the program described in this amendment.

RADIOLOGICAL HEALTH JUSTIFICATION

BACKGROUND

The Public Health Service has been conducting off-site operations since 1955 to assess the possible hazards which may be associated with nuclear testing in Nevada within the area extending 200-300 miles from the Nuclear Test Site. The Division of Radiological Health has also carried out an extensive nationwide environmental surveillance program. In addition, the Division has directed a major share of its research efforts to biological effects of radiation particularly the radiostrontiums and the radioiodines.

The August 1963 hearings of the Joint Committee on Atomic Energy, Congress of the United States, resulted in renewed interest concerning the question of possible injury to residents in proximity to the Nevada Test Site as a result of fallout from weapons tests in Nevada. The Surgeon General stated in a press release dated August 23, 1963, that the Public Health Service was intensifying its studies relevant to this question. This program has included epidemiological studies of selected causes of morbidity and mortality potentially related to radiation exposure with special attention directed to thyroid neoplasms and to blood diseases and also supportive experimental radiobiologic studies.

Public Health Service field investigations began with the collection of case histories on Utah and Nevada patients with thyroid disease who were hospitalized any time after 1948. All records of thyroid surgery in individuals under 30 years of age were checked. There is a suggestion of an increased thyroid cancer incidence in the Utah area during the period 1958-1962 over the period 1948-1952 in certain age and sex groups. However, further time and similar data from other areas for control purposes will be necessary before any conclusions can be drawn or clear trends determined with respect to geographical or temporal patterns.

Leukemia mortality in Washington and Iron Counties, Utah, from 1950-1964 was also investigated. Preliminary results from this investigation indicate a greater number of cases of leukemia in these counties than would be predicted on the basis of the nationwide incidence of leukemia. There were 28 cases found where 19 would have occurred on the basis of national rates. The significance, if any, of this finding cannot be evaluated at the present time.

The most recent phase of the population study is a comparison of the findings by physical examination for thyroid abnormalities among school children in Washington County, Utah, and Graham County, Arizona. The preliminary results of this study indicate a higher prevalence of thyroid nodules in the 2,050 school children in Washington County, Utah, than in the 1,442 school children in Graham County, Arizona, the latter being an ethnically similar group who, through the years, are believed to have received very little exposure from fallout compared to the Utah group. Further investigations are necessary in

order to characterize the etiology and pathology of the observed lesions. Although the findings at this point are equivocal, possible significance is reinforced by similar findings among Rongelap Island children who were exposed to high levels of fallout in 1954 resulting from a Pacific weapons test. In the Pacific the air concentrations were undoubtedly higher, but the length of exposure was less and the possibility of unconcentrating radioactive iodine in milk did not exist.

It is generally accepted that the thyroid gland of infants and children is quite radiosensitive with respect to tumorigenesis based on many reports in the literature that clearly associate a high prevalence of thyroid neoplasia as late as 10 - 20 years following therapeutic exposures (generally, air doses greater than 100 R) to the head and neck of infants and children. The main concern over the thyroid radiosensitivity, with respect to fallout contamination, centers on several radioactive iodine isotopes which contribute prominently to the spectrum of fresh fission products and which behave metabolically in a manner identical to stable iodine; i.e., the radioactive isotopes of iodine also are selectively concentrated in the thyroid gland where most of the ionizing radiation energy is then expended. These radioisotopes of iodine would be concentrated in fresh milk if land on which dairy cattle graze is contaminated with fresh fallout. Therefore, there is concern whether the internal thyroid dose from radioiodine inhaled or consumed, particularly through milk, is a hazard to children.

The Division of Radiological Health considers that these preliminary findings from Rongelap Island and Utah are of extreme importance and necessitate much greater study effort than currently provided for in its current Fiscal Year 1967 appropriation request. The importance of these new findings is substantiated by the reaction and interest manifested by the President's Office of Science and Technology; the Surgeon General, the Secretary, Department of Health, Education, and Welfare; Federal Radiation Council; and the Atomic Energy Commission. Each has expressed concern about these findings and emphasizes the need for concerted scientific investigations to clarify what etiologic role, if any, contamination from fallout plays in the production of thyroid tumors.

Also the findings and recommendations of a panel of experts on thyroid disease and a panel of biostatistical experts suggested by the Office of Science and Technology, both convened by the Surgeon General, further substantiate the need for extensive and intensive studies to clarify the significance of radiation in the occurrence of thyroid abnormalities.

To carry out this expanded program in 1967 will require an amendment of $1,200,000 and 27 positions to the original 1967 estimates. The original estimates for both 1966 and 1967 included $286,000 and 12 positions to cover our current efforts in this area. It is now planned to expand 1966 efforts to $386,000 and 16 positions. This is an increase of $100,000 and four positions for 1966. The 1966 increase will be accomplished through administrative savings currently being made through more prudent management of expenditures for travel, communications and equipment. To accomplish these program efforts on a full scale basis in 1967 will require $1,586,000 and 43 positions. This is an increase of $1,200,000 and 27 positions over the original 1967 estimates.

NEW AND EXPANDED STUDIES ON THYROID TUMORIGENS

As a result of this new information and the reactions and recommendations noted above, the Division of Radiological Health is programming a redirection of its biomedical programs to place greater emphasis on studies that may clarify the etiologic significance of radiation in the production of thyroid tumors. However, other program commitments and budgetary and personnel ceilings provide only very limited latitude for redirection of effort.

Recognizing the national policy implications involved with regard to continued use of the Nevada Test Site and the apprehension existing in surrounding States concerning the possibility of as yet unknown populations who may also be involved, the Division of Radiological Health is immediately reprogramming its epidemiological and supportive biomedical and environmental programs to place greater emphasis on the relative significance of radiation in the production of thyroid tumors. However, other program commitments and budgetary and personnel ceilings permit only limited latitude for such redirection of effort.

This amendment would allow further expansion of ongoing studies and a significant effort in those important areas of epidemiology, retrospective dosimetry, and the study of environmental goitrogens in the locales of interest. Without the amendment requested it is probable that definitive answers will not be found for a period of five to ten years. With this amendment, resolution of the important questions may be expected within a period of two to five year.

Goals and Program Objectives

In order to clarify the etiologic importance of radiation in the production of thyroid tumors, there should be coordinated and directed efforts to study various demographic, physiologic and morphologic factors concommitantly with radiation exposure.

Accordingly, the following broad study objectives are proposed for epidemiologic studies and, where appropriate, for supportive radiobiologic studies:

(1) To establish the prevalence of morbidity and mortality of thyroid abnormalities in selected irradiated and comparison human population groups with concomitant investigation of pertinent family and individual health and environmental factors.

(2) To quantify the relationships between irradiation dose and induction of thyroid tumors including the importance of irradiation dose parameters such as dose rate, quality, and type of radiation and tissue distribution of dose in tumorigenesis.

(3) To determine the significance of age at time of exposure of the thyroid gland in producing thyroid tumors.

(4) To clarify the relative tumorigenic importance of direct and indirect effects of irradiation on the thyroid gland.

(5) To determine the influence of metabolic and endocrinologic factors and age and sex on the pathogenesis of thyroid lesions.

The Division of Radiological Health currently has under way, or in an advanced stage of planning, a series of mutually supportive epidemiologic and radiobiologic studies programmatically directed toward the broad objectives listed above. These studies, very briefly described, are as follows:

Epidemiologic and Field Studies

1966 Estimate Revised		1967 Estimate Revised		Increase	
Pos.	Amount	Pos.	Amount	Pos.	Amount
4	$192,000	18	$992,000	+14	+$800,000

Radiation and Thyroid Injury

Population Studies in Utah, Nevada, and Select Comparison States

Objectives: To define the characteristics of the morbidity of thyroid disease and mortality of leukemia in the populations of Utah and Nevada in an effort to determine if the patterns are different in sections of the States presumed to have high concentrations of fission product radionuclides from weapons testing fallout versus sections having low or no fallout from testing.

To define the prevalence of thyroid disease and the incidence of leukemia in other selected states and counties to use as "base lines" for interpretation of the findings in Utah and Nevada.

Summary: The leukemia mortality data from 1948-1963 for Utah-Nevada are being analyzed. Pathology reports and pertinent case histories for all patients undergoing thyroid surgery in the two States for the same period are also under anlysis. Similarly, the results of the thyroid examinations conducted on school children in Washington County, Utah, and Graham County, Arizona, will be tabulated after additional clinical follow-up is completed. Plans are underway to obtain similar data in Utah on other age groups, populations of other counties in the same geological location with similar climatic and demographic characteristisc and in groups having different ethnic and socio-economic backgrounds living in different geographical locations. It is proposed that at least six additional school populations with approximately 2,000 students each be studied in Utah and Arizona and four-six comparable groups in other States. Other states being tentatively considered are West Virginia, Oregon, Nebraska and Colorado.

Study of Morbidity and Mortality of Thyroid Disease

Objectives: To establish distribution patterns of diagnosis of thyroid disease by age, sex, type of disease, locale, and year;

To estimate the distribution patters of the onset of first symptoms of thyroid disease by age, sex, and type of disease;

To establish the distribution of survival of thyroid cancer patients by sex, age at diagnosis, and type of tumor; and,

To establish the distribution of the causes of death as entered on death certificates of patients previously diagnosed as having thyroid cancer.

Summary: The collection of thyroid pathology data and case histories as collected in Utah and Nevada from 1948-1963 will be extended to other States including the State of Arizona. Priority will be given to the collection of these data from States in which population studies referred to above are being performed. Efforts will be made to work back from known mortality statistics to develop data on morbidity/mortality relationships for thyroid cancer and to develop morbidity data for all thyroid diseases among persons under thirty years of age.

Retrospective Studies of Thyroid Cancer

Objectives: To assemble a roster of cases of newly diagnosed thyroid cancer with appropriate histories in an effort to delineate possible radiation etiological factors and latent periods.

Summary: Dr. Theodore Winship, Washington Hospital Center, Washington, D.C., has been accumulating tissues and histories of radiation exposure in children diagnosed as having thyroid cancer before the age of 15 [illegible] years. It is proposed to expand this series to older age groups by [illegible] all newly diagnosed thyroid cancer patients and obtaining a more detailed history of irradiation exposure as well as pertinent disease history in several large medical centers. Contracts would be made with Washington Hospital Center and several other large medical centers to assemble this proposed roster.

Diagnostic ^{131}I in Children

Objectives: To develop cooperative studies of the occurrence of thyroid tumors following the administration of microcurie doses of radioiodine in children in the dose range utilized in diagnostic thyroid function studies.

Summary: From data on a national questionnaire to isotope licensees and intensive follow-up of records of 17 large medical centers, it is estimated that over 20,000 children received diagnostic doses of ^{131}I prior to 1963 with about one-half of the doses being delivered prior to 1956. It is estimated that the mean absorbed thyroid dose prior to 1956 was 50-100 rads. Rosters are being developed for possible follow-up studies of the questionnaire-type as well as, on a selective basis, clinical follow-up studies, to determine whether thyroid doses of ^{131}I in the diagnostic range are tumorogenic.

Thyroid Tumors Following X-ray Therapy for Benign Conditions in Infants and Children

Objectives: To support and coordinate studies which investigate the association of X-ray therapy radiation dose to head, neck, and mediastinum in children with the subsequent occurrence of tumors.

Summary: Studies reported by the Universities of Rochester and Cincinnati show [illegible] continuing follow-up of irradiated children [illegible] information on the incidence of diseases in these groups, particularly with respect to thyroid tumors. An additional series of cases at [illegible] General Hospital now being brought under study will make available for follow-up studies a total of approximately 5,000 children exposed to irradiation of the head and neck with [illegible] controls. It is [illegible] that protocols for study and continuous follow-up, including [illegible] examination, be developed for this total group of children [illegible] efforts be directed to comparing health history, goiter history, goitrogens, and other factors in appropriate subsamples of the population.

Radiobiologic Studies

1966 Estimate Revised		1967 Estimate Revised		Increase	
Pos.	Amount	Pos.	Amount	Pos.	Amount
10	$154,000	17	$354,000	+7	+$200,000

Supportive radiobiological investigations have the following objectives:

Objective 1: To provide information on the distribution and dose of ^{131}I to the embryonic thyroid and its possible teratogenic effect.

Objective 2: To evaluate the frequency and persistence of chromosome aberrations that are produced in thyroid tissue as a function of dose comparing X-ray and ^{131}I exposures and to determine the association of observed chromosome abnormalities to the induction of thyroid tumors.

Objective 3: To determine the effect of gonadal and pituitary hormones on the induction and development of thyroid tumors after radiation exposure.

Objective 4: To determine age sensitivity in radiation thyroid tumorigenesis.

The studies are conducted using chinese hamsters, rats, and dogs under controlled and known radiation exposure situations. Work will be conducted at existing laboratory facilities of the Division and the Collaborative Radiological Health Animal Research Laboratory at Colorado State College. Tentative plans are to coordinate the in-uterine phase of this study at Colorado with related experiments planned at the University of California (Davis).

Environmental Studies

1966 Estimate Revised		1967 Estimate Revised		Increase	
Pos.	Amount	Pos.	Amount	Pos.	Amount
2	$40,000	8	$240,000	+6	+$200,000

Investigation of Environmental Goitrogens in Study Populations

Objectives: To establish the presence or absence of known goitrogenic factors in the environment of study populations.

Summary: Environmental studies will be undertaken in the same locales that are under study in the previous project to identify major dietary constituents, including minerals in water, milk, and food, goitrogens in foods, as well as potential goitrogenic factors related to peculiarities of the region or habits and needs of the study populations. Efforts will be made to establish the extent of exposure of selected groups and individuals to any goitrogenic factors identified.

Dosimetric Support to Epidemiologic and Radiobiologic Thyroid Studies

Objectives: To provide precise dosimetric calculations and measurements to be made in support of radiobiologic and epidemiologic studies.

Summary: Only very tenuous and conflicting estimates of internal radiation exposures are available for populations in Utah in the early 1950's. This is due to the fact that specific measurements for the radioactive iodines were not routinely made at that time. Therefore, existing data on gross beta and gamma measurements made at that time need to be correlated with concurrent special studies which did involve the measurement of a few animal thyroids for iodine, and data from later tests where both gross beta and gamma and iodine data are available for study. Data from recent experimental work will also be used. Such data combined with a study of agricultural and dietary factors will be used to construct estimates of total exposures received in the early 1950's by the populations of concern.

All the radiobiologic studies summarized above necessitate precise careful radiochemical, autoradiographic, and/or dosimetric measurements and calculations. To date, very little effort has been devoted toward reconstructing the dosimetry of the tissues or organs in which tumors ultimately developed among children receiving therapeutic irradiation. The data from the largest roster of such children suggest that irradiation of the pituitary may be an etiologic factor in producing some of the thyroid tumors. It is of the utmost importance that we try to reconstruct the dosage pattern of patients experiencing tumors to determine: (1) Whether the primary tumor sites were in a close apposition to or within the direct beam, and (2) The importance of pituitary exposure; (3) Approximate estimates of dosages to tissues of interest.