SSA-RT-A-2011-12-13

Supporting Statement A

CANCER RISK IN U.S. RADIOLOGIC TECHNOLOGISTS: FOURTH SURVEY (NCI)

December, 2011

This submission was formerly titled:

Generic Clearance to Collect Medical Outcome and Risk Factor Data from a
Cohort of U.S. Radiologic Technologists
(2003 OMB submission)
&
Genetic Studies in a Cohort of U.S. Radiologic Technologists
(2008 OMB submission)

OMB No. 0925-0405, Expiration Date: 2/28/2011

Submitted by

Martha S. Linet, Principle Investigator and Chief
Radiation Epidemiology Branch
Division of Cancer Epidemiology and Genetics
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20892

Contact Person:
Michele M. Doody, M.S.
Contracting Officer Technical Rep
11300 Mountain View Road
Damascus, Maryland 20872
Phone: 301-414-0308
Fax: 301-414-0308
E-mail:
doodym@mail.nih.gov

TABLE OF CONTENTS

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary....1

2. Purpose and Use of the Information Collection....4

3. Use of Improved Information Technology and Burden Reduction....6

4. Efforts to Identify Duplication and Use of Similar Information....7

5. Impact on Small Businesses or Other Small Entities....11

6. Consequences of Collecting the Information Less Frequently....11

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5....12

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency....12

9. Explanation of Any Payment or Gift to Respondents....13

10. Assurance of Confidentiality Provided to Respondents....13

11. Justification for Sensitive Questions....15

12. Estimates of Annualized Burden Hours And Costs....16

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers....18

14. Annualized Cost to the Federal Government....18

15. Explanation for Program Changes or Adjustments....19

16. Plans for Tabulation and Publication and Project Time Schedule....19

17. Reason(s) Display of OMB Expiration Date is Inappropriate....19

18. Exceptions to Certification for Paperwork Reduction Act Submissions....20

ATTACHMENTS

Attachment 1: Information Collection Instrument
A. Core module
B. Nuclear medicine (NM) module
C. Fluoroscopically-guided (FG) interventional module

Attachment 2: Questionnaire Contact Letters

Attachment 3: Medical Validation Contact Letters

Attachment 4: HIPAA Authorization for Medical Records

Attachment 5: Institution Review Board approvals from the National Cancer Institute and The University of Minnesota

Attachment 6: Bibliography

Attachment 7: Privacy Act Memo

Attachment 8: Privacy Impact Assessment (draft to NCI) (PIA)

The 2008 submission (OMB No. 0925-0405, expired 02/28/2011) was a generic and this submission is now a non-generic, and thus it is a “new” IC.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

With this submission, the NCI seeks to obtain OMB approval to conduct a fourth cohort follow-up survey in an ongoing cohort study of U.S. Radiologic Technologists (USRT) to collect updated information on cancer and other medical outcomes, personal medical radiation procedures, and other risk factors from all participants, plus detailed employment data from subgroups of participants who performed or assisted with fluoroscopically-guided or radioisotope procedures.

The Radiation Epidemiology Branch (REB), Division of Cancer Epidemiology and Genetics, of the National Cancer Institute (NCI) is authorized under the Public Health Service Act, Section 411, [42 USC 285a] to collect information to generate hypotheses concerning environmental and host determinants of cancer. It is the mandate of REB to conduct a broad-based research program to identify, understand, and quantify the risk of cancer in populations exposed to medical, occupational, or environmental radiation. Overall, the REB mission is: to characterize and quantify the carcinogenic risks of radiation; to address radiation issues of public health and clinical concern; to enhance understanding of radiogenic and other carcinogenic mechanisms; and to improve dosimetric and statistical methods for risk assessment. The primary objectives of this epidemiologic follow-up study are: (1) to quantify radiation dose-response risks for cancers and other diseases with long-term cumulative exposure to protracted low- to moderate-dose occupational and personal medical ionizing radiation; (2) to assess risks of cancer

and other diseases from occupational exposure to new and evolving radiologic modalities, in particular, radioisotope and fluoroscopically-guided procedures; and (3) to assess risks of skin and other cancers associated with historic solar ultraviolet radiation exposure.

Researchers at the National Cancer Institute and the University of Minnesota have followed this nationwide cohort of 146,000 radiologic technologists since 1982 (Boice *et al*, 1992; Doody *et al*, 1998; Mohan *et* al, 2003; Sigurdson *et al*, 2003). The U.S. Radiologic Technologists (USRT) cohort is one of the largest populations of medical radiation workers studied to date (Yoshinaga *et al*, 2003), and the only one with substantial numbers of women, extensive covariate data, both incident and death outcomes, and estimated occupational, personal medical, and ultraviolet radiation (UVR) doses. More than 110,000 technologists completed at least one of three comprehensive questionnaire surveys administered during 1983-2005 and about 22,000 of the original target population of 146,022 are deceased. The first survey (OMB No. 0925-0164, expiration 7/31/1989) was mailed during 1983-1989 to 132,454 known living radiologic technologists, of whom 90,305 (68%) responded (Boice *et al*, 1992). The second survey (OMB No. 0925-0405, expiration 9/30/1999) was mailed during 1994-1998 to 126,628 known living technologists and completed by 90,972 (72%) (Sigurdson *et al*, 2003). Both surveys included detailed questions about employment as a radiologic technologist, family history of cancer, reproductive history, height, weight, other cancer risk factors (such as alcohol and tobacco use), history of personal diagnostic and therapeutic medical radiation procedures, and information on cancer and other health outcomes. The third survey (OMB No. 0925-0405, expiration 2/28/2007), was mailed or administered by telephone during 2003-2005 to 101,694 living cohort members who completed at least one of the two earlier surveys, and 73,625 (72%) responded. The third questionnaire elicited information on medical outcomes to assess radiation-

related risks, detailed employment data to refine the occupational radiation dose estimates, and behavioral and residential histories for estimating lifetime ultraviolet (UV) radiation exposure for studies of melanoma and non-melanoma skin cancer.

Findings from this study will address an important gap in the scientific understanding of ionizing radiation dose-rate affects, i.e., whether cumulative exposures of the same magnitude have the same health effects when received in single or a few doses over a very short period of time (as in atomic bomb or therapeutic exposures) or in many small doses over a protracted period of time (as in medical or nuclear occupational settings). The public health implications of quantitative risk information for chronic low- to moderate-dose radiation exposures are consequential because it is this level of radiation exposure that is of most concern to those employed in the medical field and to the general population in which primary radiation exposures are from medical or environmental sources. Additionally, with dramatic increases in use of fluoroscopically-guided interventional and newer radioisotope procedures, it is critical to identify early any increases in cancer or other serious disease risks associated with occupational radiation exposures to ascertain whether existing radiation protection measures are adequate. Also, monitoring of health risks in radiologic technologists can provide early warning of patient risks. Finally, the USRT Study is the only nationwide cohort study, to our knowledge, that has collected lifetime information on residence and time spent outdoors (weekday and weekend) from subjects residing in a broad range of latitudes, and linked the data to residential ambient solar UVR databases. This lifetime UVR exposure data, in conjunction with newly identified cancers and other medical conditions, will provide a unique opportunity to examine prospectively disease risks from solar UVR exposure among subjects residing in a broad range of latitudes, as well as potential effect modification of cancer risks from occupational or personal

medical radiation exposures by solar UVR estimated levels (Karagas *et al*, 2006) or by host solar UVR susceptibility factors (Yoshinaga *et al*, 2003).

2. Purposes and Use of the Information Collection

This is an epidemiological cohort research study. Long-term cancer and other disease risks for the entire cohort (median age, 62), which is now entering ages of rising baseline cancer risks, and assessment of other outcomes, including selected benign malignancies, cardiovascular disease and cataracts, will be based on new cancer and other disease outcomes to be collected in the fourth survey.

The results will be used to further our understanding of the relationship between exposure to occupational and medical ionizing radiation and the risks of cancer and other medical conditions. Additionally, the nationwide cohort distribution, with widely varying solar ultraviolet (UV) radiation exposures, provides a rare opportunity to assess melanoma and non-melanoma skin cancer risks associated with ultraviolet radiation. We are not aware of any other study population in which quantified individual radiation dose estimates from occupational, medical, and ultraviolet exposures are available, as well as extensive covariate data and ongoing follow-up for medical outcomes.

The 2003 submission (OMB No. 0925-0405) encompassed both a third and fourth follow-up survey of the general cohort; however the fourth survey was never conducted and is being requested now. In 2003, it was estimated that there would be 79,800 participants in the general cohort that would complete the fourth survey. Owing to continued losses in follow-up and increases in deaths over time, our current estimate of 65,100 responders reflects a 70%

response rate among an estimated 93,000 previous questionnaire responders who are still living and have a known address.

The 2008 submission (OMB No. 0925-0405, expired 02/28/2011) was a generic submission, focused on assessing genetic and molecular risk factors for cancer, was also proposed in the 2003 submission. Part of the 2008 submission was approved with changes and another part was withdrawn at the request of the submitter. The participants for the 2008 submission were a small sub-cohort of approximately 10,000.

This submission is being requested to administer a fourth cohort follow-up survey during the next three years. The target group for the fourth survey is approximately 93,000 living and located cohort members who completed at least one of the three previous surveys. The fourth survey will collect information on new cancers and other disease outcomes, detailed work patterns and practices from technologists who worked with radioisotopes and fluoroscopically-guided interventional radiography procedures, and new or updated risk factors that may influence health risks. New occupational and medical radiation exposure information will be used to improve radiation dose estimates.

The fourth survey is divided into three modules:

- **Attachment 1A** – CORE Module. The core module includes questions about general work history as a medical radiation technologist, cancer and other serious disease outcomes, personal medical radiation exposures, and other risk factors (e.g. smoking, reproductive and gynecologic history, family medical history, physical activity, vitamin supplement use, sun exposure, sleep patterns, night shift work) and will be completed by all participants.

- **Attachment 1B** - Nuclear medicine (NM) module will be completed by a subset within the overall target group of approximately 30,000 radiologic technologists who previously reported performing nuclear medicine procedures at least once a month for a year or more.
- **Attachment 1C** - Fluoroscopically-guided (FG) interventional module will be completed by a subset within the overall target group of approximately 27,000 radiologic technologists who previously reported performing interventional fluoroscopy procedures at least once a month for a year or more.

[Note : The target populations for the NM and FG modules are not mutually exclusive as approximately 10,000 radiologic technologists performed both types of procedures.]

Medical outcomes will be used to assess radiation-related and other disease risks. Other risk factor data will be used to adjust radiation-related risk estimates and evaluate new causal factors. It is anticipated that there will be 8,800 new cancers and other medical conditions of interest in which a medical validation (**Attachment 3**) will be pursued could be completed.

Copies of the fourth survey modules (**Attachments 1A-1C**), questionnaire contact letters (**Attachment 2**), medical validation contact letters (**Attachment 3**), and HIPAA authorization for medical records (**Attachment 4**) are provided.

3. Use of Improved Information Technology and Burden Reduction

The information to be collected from cohort members directly will be in media that can be optically scanned by computer. Every effort has been made to minimize the length of the questionnaire and to format it in a manner that will optimize clarity and minimize the burden on the respondent. Responses for most questions involve checking a box or inserting a number; only a few questions allow for limited write-in responses. Skip patterns will reduce burden by

allowing subjects to skip over questions that are not applicable. The use of improved information technology will lead to lower error rates by avoiding transcribed answers and potential distortion of information.

The Privacy Impact Assessment (PIA) is in the process of being reviewed by the NCI Privacy Act Coordinator (**Attachment 8**). PIAs will be conducted on both the University of Minnesota and the Information Management Services, Inc. (computing support services contractor).

4. Efforts to Identify Duplication and Use of Similar Information

Although cancer risks following ionizing radiation exposure have been widely studied, to date quantitative estimates of external radiation-related cancer risk have been derived largely from studies of the Japanese atomic bomb survivors (ICRP, 1991; Tokunaga *et al*, 1994; Land *et al*, 1994; Preston *et al*, 1994; Land *et al*, 1995; Pierce *et al*, 1996) and therapeutically-irradiated patients (Hildreth *et al*, 1985; Shore *et al*, 1986; Ron *et al*, 1988; Shore *et al*, 1993; Mattsson *et al*, 1993; Karlsson *et al*, 1998; Travis *et al*, 2002; Preston *et al*, 2002). Cancer risk estimates from the Japanese atomic bomb survivor data and irradiated patients are based on a single acute radiation exposure or a few high radiation exposures over a relatively short period of time, respectively. In contrast, there is a relative paucity of comparable quantitative risk estimates for cancer from epidemiological data of chronic low- to moderate-dose radiation exposures that occur more commonly in occupational and environmental settings. Animal studies suggest that repeated, low-dose exposures may not have the same effect as a single or a few high dose exposures because of the opportunity for DNA repair.

A large number of studies have been conducted on nuclear industry workers (UNSCEAR, 2000; UNSCEAR, 2006) who are predominantly male and generally experienced lower cumulative radiation doses than U.S. radiologic technologists owing to stringent radiation protection standards established when nuclear plants were first built. In contrast, there were no recommended threshold levels for radiation protection during the initial 39 years following discovery of x-rays, and the recommended threshold levels were quite high in the early years (Inkret *et al*, 1995; ICRP, 1990). A pooled analysis of nuclear workers in 15 countries identified a significant excess risk for all solid cancers that was strongly influenced by an increased risk for lung cancer (Cardis *et al*, 2005). Risks were also elevated for other smoking-related respiratory diseases, suggesting that confounding by smoking may be responsible for at least some of the excess risk observed for all solid cancers. The USRT cohort is primarily female, with major cancer risks not shared by the largely male nuclear workers. Thus, the cancer risk data from the USRT health study will help fill an important gap in our knowledge concerning the carcinogenic and other serious health risks from chronic low- to moderate-dose radiation among females in a western population.

A comprehensive review of 270,000 medical radiation workers who first began working over a period spanning more than 80 years (Yoshinaga *et al*, 2004) found consistently elevated risks of leukemia, with notable excesses before or during the 1920s and smaller increases in subsequent decades. Estimated risks for skin and female breast cancer varied by study and years of employment. Findings for other hematopoietic (e.g., lymphoma and multiple myeloma) and solid tumors (*e.g.*, lung, stomach, thyroid, pancreas and others) were not as consistent (Court Brown and Doll, 1958; Smith and Doll, 1981; Matanoski *et al*, 1984; Berrington *et al*, 2001; Sont *et al*, 2001). Total cancer mortality was elevated in UK radiologists practicing for 40 years

or more, but the results were based on small numbers (Berrington *et al*, 2001). Dose information on the individual level is not available for cohorts of medical radiation workers (UNSCEAR, 1994), except for limited and problematic dose estimates for approximately 20,000 Chinese medical radiation workers of both sexes (Wang *et* al, 2002) and 16,000 Japanese male radiologic technologists (Yoshinaga *et* al, 1999). A large study of Canadian radiation-exposed workers with incomplete dose data does not provide separate risk estimated for medical radiation-exposed workers (Sont *et al*, 2001). None of these epidemiologic studies have described radiation dose-response risks. Previous studies of medical radiation workers have not examined risks associated with other medical conditions (e.g. benign tumors, benign breast disease, cataracts, cardiovascular diseases).

USRT researchers have identified increased risks for melanoma (Freedman *et al*, 2002), non-melanoma skin (Yoshinaga *et al*, 2005), leukemia (Linet *et al*, 2005), breast (Mohan *et al*, 2002; Doody *et al*, 2006), and thyroid (Zabel *et* al, 2006) cancers, but not lung cancer (Rajaraman *et el*, 2006), plus elevated risks for circulatory disease mortality (Hauptman *et al*, 2003) and cataracts (Chodick *et al*, 2008) with surrogate exposure measures, such as year first worked or number of years worked before 1940 or 1950. Quantitative cancer risk estimates for U.S. radiologic technologists are awaiting final enhancements to a recently completed comprehensive dose reconstruction, which provides, for the first time, annual and cumulative occupational radiation badge and 12 organ dose estimates for individual technologists (Simon *et* al, 2006; Simon *et al*, 2011; Simon *et al*, in press). The availability of specific organ doses and large number of radiation-exposed women offers a rare opportunity to study effects of low- to moderate-dose radiation exposure on breast and thyroid cancers, the two most sensitive organ sites for radiation carcinogenesis in women.

The USRT study has previously shown good correlation for estimated occupational as well as questionnaire-ascertained personal medical radiation exposures with biodosimetry (Bhatti *et al*, 2007; Sigurdson *et al*, 2008; Bhatti *et al*, 2010). Historical organ doses received by USRT cohort members were derived mainly from film badge readings and assumptions of x-ray energies typical of radiography and fluoroscopy. However, about 20% of the USRT cohort worked with radioisotopes, and currently, doses to deep-seated tissues (red bone marrow, for example) for those technologists are likely to have been underestimated because the penetration of the gamma rays emitted from isotopes is typically greater than the penetration of x-rays used in radiography and fluoroscopy. Additional work history data to be collected on the fourth survey will improve estimated doses for these individuals.

Many ecologic and case-control studies have linked lower latitudes of residence (a proxy for UVR exposure) with decreased cancer risks (Garland and Garland, 1980; Gorham *et al*, 1990; Freedman *et al*, 1997; Freedman *et al*, 2002; Grant, 2003). Analytic epidemiologic studies of breast and prostate cancer and non-Hodgkin lymphoma have shown protective associations with reported solar UVR exposure (John *et al*, 1999; John *et al*, 2004; Hartge *et al*, 2006; Knight *et al*, 2007; Kricker *et al*, 2008), and a few have identified specific periods of life (adolescence or early adult years) when solar UVR exposures appear to result in subsequent protective effects (Knight *et al*, 2007; Kricker *et al*, 2008). Overall, experimental, residential and limited numbers of epidemiologic studies have shown largely protective associations for cancers other than skin cancer, but relatively few studies have examined lifetime UVR exposure and risks of malignancies other than skin cancer, and most of these have been case-control studies. The availability of lifetime UVR dose estimates for USRT cohort members derived from residential and sun exposure data collected on the third survey and linked with satellite UVR measurements,

along with new medical outcomes to be reported on the fourth survey, will allow assessment of prospective cancer risks related to lifetime UVR exposures.

5. Impact on Small businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The fourth follow-up survey will collect detailed information on occupational, personal medical, and ultraviolet radiation exposures, personal medical history, and other disease risk factors from all living and located technologists who completed at least one of three prior surveys (~93,000). Information will be collected only one time during the 3-year period.

Occupational, personal medical and ultraviolet radiation exposures are essential for estimating ionizing and ultraviolet radiation doses. Medical outcomes are needed to assess radiation-related cancer and other disease risks. Updated and new information on selected non-radiation risk factors (such as family history of cancer, reproductive history, cigarette smoking) may confound risks associated with radiation dose and will be included in radiation dose-response risk models.

The consequence of not collecting these data is that NCI will not be able to evaluate the long-term risks of cancer and non-cancer medical conditions associated with occupational, personal medical and ultraviolet radiation exposures.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require collection to be conducted in a manner inconsistent with Guidelines in 5 CFR 1320.5.

8. Comments in Response to the *Federal Register* Notice and Efforts to Consult Outside Agency

In compliance with 5 CFR 1320.8(d), a notice of proposed data collection was published in the Federal Register on September 21, 2011 (76 FR 58520). Comments were solicited on the proposed information collection. One public comment was received from a nuclear medicine expect who has also served as a consultant to this project. He suggested that it would be best to ask the radiation technologists the number of procedures performed *per month* rather than *per week* because of the infrequency of some procedures. A pre-test is planned and this suggestion will be asked. Should the survey change, a change request will be submitted to OMB for review.

Financial support for this study is derived from the Intramural Research Program of the National Cancer Institute, Division of Cancer Epidemiology and Genetics, Radiation Epidemiology Branch, This study is being conducted in collaboration with researchers in the Division of Environmental and Occupational Health, School of Public Health, University of Minnesota (Bruce H. Alexander, PhD, Project Director; telephone 612-625-7934, email balex@umn.edu). Permission was obtained from Jerry B. Reid, PhD, Executive Director of the American Registry of Radiologic Technologists (telephone 612-687-0048, www.arrt.org) to contact study subjects identified from Registry records. Both of the above-mentioned individuals provide regular on-going consultation with respect to the availability of data, clarity of instructions and reporting format, and data elements recorded.

9. Explanation of Any Payment or Gift to Respondents

In an earlier randomized trial of the use of financial incentives, we found that inclusion of a small monetary incentive (as little as $1.00) with the second follow-up mail questionnaire significantly improved questionnaire response (Doody *et al*, 2003). However, because this cohort is so large, it is cost-prohibitive to include even a $1.00 bill with the planned questionnaires.

10. Assurance of Confidentiality Provided to Respondents

This study is supported by Contract HHSN261201000139C, entitled "Support for Epidemiological Studies of Cancer Risk in Radiologic Technologists", with the University of Minnesota. Research involving human subjects conducted by the University of Minnesota is covered under Assurance of Compliance number FWA00000312. This study has been reviewed and approved annually by the Institution review boards at the National Cancer Institute (protocol number OH97-C-N053) and the University of Minnesota (protocol number 8005M02489) **(Attachment 5)**. It has been determined that the Privacy Act applies to this collection of information. The data collection is covered by NIH Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD". The information will be retrieved and maintained by personal identifiers, and data analysis will involve critical parameters relevant to the targeted audiences (e.g., personal medical histories, such as radiation-related illnesses, medical irradiation, gynecologic and reproductive histories, cigarette smoking, sunlight exposure, participant names, date of birth, gender, home address, telephone number) **(Attachment 7)**.

The University of Minnesota will subcontract for services with an optical scanning corporation for all data instrument printing and scanning activities. University study staff

members are cognizant of the sensitive nature of the data on the basic cohort of radiologic technologists obtained from the American Registry of Radiologic Technologists (ARRT) and have proven their ability to provide secure and confidential management of the data for this population over more than 30 years. The subcontractor will be required to provide the same level of security.

The study will utilize a data capture method that involves optical scanning of all data collection instruments. The data forms will be prepared by the subcontractor for mailing during the 3-year study period. After receiving updates of subject addresses from the University and RTI International, the subcontractor will subsequently print and mail all data collection instruments within 30-days time. All completed forms will be returned directly to the subcontractor, to be opened, edited, and scanned. All data scanned from the data forms will be delivered to the University of Minnesota and stored in computer files without personal identifiers. Hardcopy scanned questionnaires will be returned to the University and stored by "batch" and "serial" number assigned during the scanning process. No data forms will be indexed by name, social security number, ARRT registration number, or any other personal identifier. All hardcopy questionnaires will be stored in secure locked rooms while at the University or at the subcontractor. Only authorized project staff will have access to these areas.

Medical records obtained to validate cancer diagnoses, State cancer registry records, and death certificates, which will also contain subjects' personal identifying information, will be stored in locked file cabinets at the University of Minnesota. Data from these records will be linked to the respondent by person-specific study identification number only.

All study records will be kept in locked files in locked study offices. Electronic data are stored on password-protected computers. Access to the study offices and computer files is

strictly limited to study staff. Access to data is limited to only those data files needed by specific staff members to perform their specific jobs. Data will be stored by ID number only in separate files from study identifiers (e.g. participant names). Data tapes containing no subject personal identifiers will be delivered to NCI periodically and will be accessible only to a limited number of individuals from the Radiation Epidemiology Branch, NCI and Information Management Services, Inc. (IMS) (computing support services contractor to NCI) who are directly involved in the study and who are responsible for analyzing the data.

Publication of study results will be of an aggregate and statistical nature only. Individuals will not be identified or identifiable in any report from the study. All contractor personnel working on this project and who have access to subject identifying information have received training in protecting the confidentiality of study subjects, and all NCI contractors have provided assurances of confidentiality. A NIH Certificate of Confidentiality (COC) covers the genetic studies but does not currently cover the cohort questionnaires. Pending IRB approval for the fourth cohort survey, we will request a COC for this questionnaire.

As this is a prospective cohort study, there are no current plans to dispose of the information obtained. The data will be stored indefinitely unless a decision is reached not to conduct any further follow-up of this study population. Should that decision be made at a future date, all items containing personal identifiers will be destroyed through shredding, degaussing, or incineration at the direction of the Contracting Officer's Technical Representative, NCI.

11. Justification for Sensitive Questions

Personally identifiable information (PII) will be collected and maintained by the University of Minnesota, such as participant names, home addresses, and telephone numbers.

All data submitted to NCI or other contractors will be identified by study ID number only and used for statistical purposes only.

Additionally, some of the questions are considered sensitive, including personal medical histories (i.e. medical illnesses, medical irradiation, gynecologic and reproductive histories), family history of cancer, and lifestyle factors (e.g. cigarette consumption, physical activity, sun exposure). Data on medical illnesses and irradiation are necessary to assess risks of cancer and other conditions associated with occupational, personal medical, and ultraviolet radiation exposure. Data on other factors (e.g. gynecologic and reproductive histories, cigarette consumption) are needed because these factors are strongly related to an individual's risk of cancer and/or other health conditions, and may confound the risks associated with radiation. This valuable cohort of radiation technologists is anticipated to be followed indefinitely for incidence and mortality from cancer and other conditions

Participants will be advised in the advance letter **(Attachment 2)**, sent prior to any mail questionnaires, that their participation is completely voluntary and that they may refuse to respond to any or all questions without penalty. Completion and return of a mail questionnaire will imply consent.

12. Estimates of Annualized Burden Hours and Costs

Eligible cohort members for the fourth questionnaire survey are living and located U.S. radiologic technologists who willingly participated in earlier investigations to quantify the carcinogenic risks of protracted low-to-moderate dose occupational radiation exposures (i.e. those individuals who completed at least one of three previous cohort surveys). Medical record confirmation of reported cancers and selected other medical conditions will be pursued from

diagnosing hospitals or physicians. The estimated annual number of respondents is 37,053 and the estimated annual hour burden is 14,746 hours. Over the course of three years of information collection, it is anticipated that there will be 111,159 respondents which will amount to 44,238 burden hours.

Table A.12-1. Estimates of Annual Burden Hours

Type of Respondent	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Hours)	Annual Hour Burden
Cohort members (overall target group)	Fourth Survey CORE Module (Attachment 1A)	21,700†	1	30/60 (0.5)	10,850
Cohort members (subgroup 1 of overall target group)	Fourth Survey NM Module (Attachment 1B)	7,000‡¶	1	20/60 (0.33)	2,333
Cohort members (subgroup 2 of overall target group)	Fourth Survey FG Module (Attachment 1C)	6,300§¶	1	10/60 (0.17)	1,050
Medical office clerks	Medical Validation (Attachment 3)	2,053£	1	15/60 (0.25)	513
TOTAL		37,053			14,746

† The fourth survey CORE questionnaire module will be mailed to approximately 93,000 radiologic technologists who completed at least one of three previous cohort questionnaires, are currently living, and have a known address. We estimate that 70% of this overall target group will complete the CORE module over 3 years (65,100 total or 21,700 per year).

‡ The fourth survey NUCLEAR MEDICINE (NM) questionnaire module will be pursued from a subset within the overall target group of approximately 30,000 radiologic technologists who previously reported performing nuclear medicine procedures at least once a month for a year or more. We estimate that 70% of the target subgroup will complete the NM module over 3 years (21,000 total or 7,000 per year).

§ The fourth survey FLUOROSCOPICALLY-GUIDED (FG) interventional questionnaire module will be pursued from a subset within the overall target group of approximately 27,000 radiologic technologists who previously reported performing interventional fluoroscopy procedures at least once a month for a year or more. We estimate that 70% of the target subgroup will complete the FG module over 3 years (18,900 total or 6,300 per year).

£ Medical validation will be pursued for 70% of an estimated 8,800 new cancers and other medical conditions of interest over 3 years (6,160 total or 2,053 per year).

¶ The target populations for the NM and FG modules are not mutually exclusive. Approximately 10,000 radiologic technologists performed both types of procedures. Based on an estimated 70% response, a total of 7,000 (2,333 per year) are expected to complete both modules.

Based on the 2010 wage and salary survey of the American Society of Radiological Technologists (https://www.asrt.org/Content/News/PressRoom/PR2010/asrtsurvey100525.aspx)

and the 2008 Department of Labor wage rates (http://www.bls.gov/oco/ocos103.htm), and allowing for an increase of 2% per year, we assumed an average hourly rate of $29.68 for radiologic technologists and $15.31 for medical record clerks. The estimated annual burden cost is $430,293 (Table A.12-2) and over a three-year information collection period approximately $1,290,879. There will be no direct costs to the respondents other than their time to complete the questionnaires or to retrieve medical validation information.

Table A.12-2. Estimates of Annualized Cost to Respondents

Type of Respondent	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Hours)	Annual Hour Burden	Wage Rate	Total
Cohort members (overall)	Fourth Survey CORE Module (Attachment 1A)	21,700	1	30/60 (0.5)	10,850	$29.68	$322,028
Cohort members (subgroup 1)	Fourth Survey NM Module (Attachment 1B)	7,000	1	20/60 (0.33)	2,333	$29.68	$69,243
Cohort members (subgroup 2)	Fourth Survey FG Module (Attachment 1C)	6,300	1	10/60 (0.17)	1,050	$29.68	$31,164
Medical office clerks	Medical Validation (Attachment 3)	2,053	1	15/60 (0.25)	513	$15.31	$7,858
TOTAL		37,053			14,746		$430,293

13. Estimate of Other Total Annual Cost Burden to Respondents and Record Keepers

No additional cost burden to respondents and record keepers is anticipated. No equipment or other technology is required for generating, maintaining, and disclosing or providing the information. There are no capital, operating, or maintenance costs to report.

14. Annualized Cost to the Federal Government

Over the three-year period for which OMB approval is being requested, annual contract costs include $460,000 to the University of Minnesota to conduct the fourth survey and pursue medical validation, as described above, and $100,000 to Information Management Services, Inc. for data analysis support. The annual cost for NCI intramural staff is $160,000. These figures include the costs of study design, subject tracing, data collection, analysis, and report writing. The total annual cost is $720,000.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A projected time schedule for the fourth questionnaire survey described in Section A.6 is displayed in Table A.17-1. All times are after initial OMB approval for the fourth survey.

Table A.17-1. PROJECT SCHEDULE

Component	Months
Information collection	0-30
Medical validation	2-32
Analysis and manuscript writing	24-36
Submit first publication	36

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons to preclude display to the OMB expiration date on the questionnaire.

16. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.