# **Supporting Statement A**

**U.S. NUCLEAR MEDICINE TECHNOLOGISTS STUDY**

**May, 2016**

This submission was formerly titled:

Cancer Risk in U.S. Radiologic Technologists: Fourth Survey

(2011 OMB submission)

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* New
* Revision

X Reinstatement with Change

* Reinstatement without Change
* Extension
* Emergency

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**SupplementARY Documents**

S1. ***U.S. Radiologic Technologists Study*** **Radioisotope Procedures Questionnaire** (OMB No. 0925-0656)

S2. ***U.S. Radiologic Technologists Study*** **General Questionnaire, Work History Section** (OMB No. 0925-0656)

#### **JUSTIFICATION**

 **Abstract**

This is a request for a Reinstatement with Change for approval for 3 years. The reinstatement is requested to administer a slightly revised version of a previously-approved and administered questionnaire to a sample of nuclear medicine technologists certified after 1980. The reason for the proposed collection is to assess the feasibility of conducting a large-scale study of radiation-related cancers and other diseases in nuclear medicine technologists.

Since 1982, the National Cancer Institute has followed a cohort of U.S. Radiologic Technologists (USRT) certified during 1926-1980 by the American Registry of Radiologic Technologists to assess radiation-related cancer and other disease risks. The field of nuclear medicine has expanded rapidly since its inception in the mid-20th century. Many radiopharmaceuticals and procedures used in previous decades are now obsolete and are being replaced by new radioisotopes and combined-modality and molecular imaging procedures. Since 1980, nuclear medicine technologists have become increasingly specialized and are performing such procedures with increasing frequency. Lead aprons are less effective in protecting workers from the higher-energy radioisotopes compared to lower-energy X-rays used in general radiologic procedures, and are seldom worn by technologists when performing nuclear medicine procedures. For these reasons, cumulative doses to nuclear medicine technologists are expected to have increased substantially over time and to be higher than those in general radiologic technologists. We hypothesize that the subgroup of radiologic technologists certified in nuclear medicine technology, especially those certified more recently, are at higher risk for certain radiation-related health outcomes than other radiologic technologists. The number of technologists in the USRT cohort who reported working with nuclear medicine procedures is relatively small, and their exposures occurred as long as 70 years ago. The objectives of the current effort are to identify a large group of U.S. nuclear medicine technologists (USNMT) certified in 1980 or later, to collect detailed work history information, and to characterize organ-specific radiation doses in a representative sample to assess the feasibility of conducting a study to quantify radiation-related disease risks in nuclear medicine technologists who worked with newer technologies in more recent years.

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

 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.

With this submission, the NCI seeks to obtain OMB approval to collect historical information from U.S. nuclear medicine technologists (USNMT) certified in 1980 or later on nuclear medicine procedures performed, radioisotopes used, related work and safety practices, and employers. The proposed USNMT Study is an expansion of the USRT Study. More recently certified nuclear medicine technologists are expected to have greater exposures to radioisotopes than the USRT members who worked with nuclear medicine procedures much earlier in time, and to be at higher risk for radiation-related medical outcomes because they likely performed nuclear medicine procedures with greater frequency and at younger ages when sensitivity to the carcinogenic action of radiation is elevated.

The primary objectives of the current feasibility effort are: (a) to identify a cohort of nuclear medicine technologists certified in 1980 or later by the American Registry of Radiologic Technologists (ARRT) and/or the Nuclear Medicine Technologist Certification Board (NMTCB); and (b) to characterize individual organ-specific occupational radiation doses from radioisotope procedures. Pending determination that both the eligible study population of nuclear medicine technologists certified in 1980 or later and the estimated occupational radiation doses are large enough to assess radiation-related cancer and other disease risks with adequate statistical power, we propose to conduct a new USNMT cohort study. Findings from this study will address an important gap in the scientific understanding of health risks associated with occupational exposure to high-energy radioisotopes. The public health implications are consequential because the increasing use of high dose nuclear medicine procedures in the diagnosis and treatment of medical conditions is associated with increased radiation exposure to both patients and medical workers.

**A.2 Purpose and Use of the Information Collection**

This is an epidemiological research study. The results will be used to determine if a cohort study of nuclear medicine technologists is feasible to address outstanding scientific questions about the relationship between occupational exposure to radioisotopes and the risks of cancer and other medical conditions. We are not aware of any other study population that can address this question.

Since 1982, researchers at the National Cancer Institute and the University of Minnesota have followed 146,000 radiologic technologists certified by the ARRT during 1926-1980 (1-5). The U.S. Radiologic Technologists (USRT) cohort is one of the largest populations of medical radiation workers studied to date (6,7), and the only one with a nationwide distribution, large number of women, extensive covariate data, both incident and death outcomes, and estimated occupational, personal medical, and ultraviolet radiation doses. More than 110,000 technologists completed at least one of four comprehensive questionnaire surveys administered during 1983-2013 under OMB No. 0925-0164 (first survey, expiration 7/31/1989), OMB No. 0925-0405 (second and third surveys, expiration 2/26/2007), and OMB No. 0925-0656 (fourth survey, expiration 4/30/2015). The fourth survey was mailed to approximately 94,000 living USRT members during 2012-2013 and collected information on medical outcomes, personal medical radiation procedures, and selected risk factors from the full group, plus detailed work histories from subgroups of technologists who worked with nuclear medicine and/or fluoroscopically-guided procedures.

 The NCI currently seeks OMB-approval for the *U.S. Nuclear Medicine Technologists Feasibility Study* Nuclear Medicine Procedures Questionnaire (**Attachment 1**) to be administered to a sample of nuclear medicine technologists certified after 1980. This request is for reinstatement with change, of the previously-approved (OMB No. 0925-0656) *U.S. Radiologic Technologists Study* Fourth Survey Radioisotope Procedures Questionnaire (**Supplementary Document S1**) that was completed by 6,300 of 9,400 (67%) general radiologic technologists certified through 1980 who reported working with nuclear medicine procedures at least once a month for a year or more in the Work History Section of the *U.S. Radiologic Technologists Study* Fourth Survey General Questionnaire (**Supplementary Document S2**). This change caused additional question development and thus the need for additional time pass the expiration date; thus causing the submission of a reinstatement with change. The General Questionnaire was completed by 58,677 of 93,787 (63%) known living study participants. The *U.S. Nuclear Medicine Technologists Feasibility Study* Nuclear Medicine Procedures Questionnaire (Attachment 1), for which OMB approval is requested, is a minor revision (see **Attachment 2**) of the previously-approved *U.S. Radiologic Technologists Study* Radioisotope Procedures Questionnaire (**Supplementary Document** **S1**). The *U.S. Radiologic Technologists Study*, Fourth Survey General Questionnaire (**Supplementary Document S2**) will not be used; however, modified versions of questions 2 and 23 will be added to the Nuclear Medicine Procedures questionnaire (see **Attachment 2**).

The proposed Nuclear Medicine Procedures questionnaire will collect historical information on years worked with nuclear medicine, specific procedures performed, radioisotopes used, and related work and radiation protection practices. Places of employment will be asked to assist in obtaining historical badge dose readings from a commercial dosimetry provider. The badge dose readings will be used in conjunction with the work history information to estimate annual and cumulative organ-specific radiation doses for individual nuclear medicine technologists.

 In this information collection we will be sending a recruitment email (**Attachment 3A**) and follow-up emails (**Attachment 3B**), as needed, to encourage individuals to participate in the study and complete the questionnaire. The emails will include a consent information sheet (**Attachment 4**), a link to the study webpage, and individual-specific login information. Before responding to the questionnaire, technologists will need to read the consent and respond to two consent questions at: (a) do you consent to complete the online survey about your nuclear medicine work history and employers; and (b) do you consent to allow study researchers to request your badge dose records from commercial dosimetry providers?

**A.3 Use of Information Technology and Burden Reduction**

Information will be collected from nuclear medicine technologists using computer-assisted web interview (CAWI) technology. Screen shots of each page are provided in **Attachment 1**. 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.

**A.4 Efforts to Identify Duplication and Use of Similar Information**

 The information that will be collected from nuclear medicine technologists certified after 1980 is not found anywhere else. Similar information was collected from general radiologic technologists certified much earlier in time (1926-1980) who reported performing at least some nuclear medicine procedures. However, owing to major changes in the field of nuclear medicine in more recent years, work histories and radiation exposures in the two groups are expected to be very different.

Cancer risks following ionizing radiation exposure have been widely studied but quantitative estimates of external radiation-related cancer risk have been derived largely from studies of the Japanese atomic bomb survivors and therapeutically-irradiated patients (8). 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.

Nuclear medicine procedures are non-invasive and involve the administration of radiopharmaceuticals to diagnose and treat a wide range of medical conditions. This field of medicine has grown and changed dramatically over the past few decades. Many radiopharmaceuticals and procedures used in previous decades are now obsolete and are being replaced by new and emerging radioisotopes and combined-modality and molecular imaging procedures (9). Nuclear medicine technologists have become increasingly specialized in performing these newer procedures, and are performing these and other nuclear medicine procedures with increasing frequency. In the U.S., the number of nuclear medicine procedures performed increased from an estimated 7 million during 1980-1982 to 18 million in 2006 (10). Although per-procedure doses to patients have generally decreased (11), the net effective dose to patients from all nuclear medicine procedures performed in the U.S. between the early 1970s and early 2000s increased 5- to 7-fold, mostly attributable to an increase in the number of relatively high-dose diagnostic cardiac procedures (12). At the same time, per-procedure occupational doses to nuclear medicine technologists and physicians are estimated to have increased (13). Although nuclear medicine procedures have provided enormous medical benefits to patients, exposure to radiation from procedures using radionuclides, especially from higher-dose or frequently-performed procedures, poses potential health risks to the medical workers who perform them.

Although annual doses to nuclear medicine technologists are well below the maximum recommended levels for individuals occupationally exposed to ionizing radiation (14-17), there is increasing evidence that protracted or repeated exposure to radiation, even at low levels, may increase risks of certain cancers and circulatory diseases. Understanding whether these associations are causal is important and relevant for worker populations and the general public (e.g., individuals exposed to repeated low-dose medical radiation procedures, such as x-rays). Cohort studies of nuclear industry workers, generally limited to follow-up for mortality rather than incidence and lacking information about potential confounding factors, have shown dose-dependent increased risks for leukemia (excluding chronic lymphocytic leukemia) (18-20), with mixed results for solid cancers (18-21). There have been fewer cohort studies of medical workers, including radiologists and radiologic technologists, but these have shown elevated incidence or mortality risks for leukemia (5, 22-26), lymphoma (23), cancers of the skin (23-24), pancreas (24), lung (23-24), breast (5, 27-28), and thyroid (29), plus ischemic heart disease and cerebrovascular disease (5).

The USRT Study is the largest study of radiologic technologists to date, but the cohort includes relatively few technologists who worked with nuclear medicine procedures and were exposed to the higher-energy radioisotopes. Based on a small subgroup of the cohort, USRT Study investigators recently reported increased risks for squamous cell carcinoma of the skin with ever performing diagnostic radionuclide procedures, for myocardial infarction incidence, all-cause mortality, and all cancer mortality with ever performing brachytherapy, and for mortality from all causes, breast cancer, and myocardial infarction with ever performing other radionuclide therapy procedures; increasing risks were also observed with greater frequency of performing these procedures, particularly before 1980 (30). Information was not available on doses so it was not possible to estimate radiation-dose response risks.

Since 1980, nuclear medicine technologists have become increasingly specialized and are performing such procedures with increasing frequency. Lead aprons are less effective in protecting workers from the higher-energy radioisotopes compared to lower-energy X-rays used in general radiologic procedures, and are seldom worn by technologists when performing nuclear medicine procedures. For these reasons, cumulative doses to nuclear medicine technologists are expected to have increased substantially over time and to be higher than those in general radiologic technologists. The number of technologists in the USRT cohort who reported working with nuclear medicine procedures is relatively small, and their exposures occurred as long as 70 years ago. Nuclear medicine technologists may receive higher cumulative radiation exposure compared to other radiologic technologists owing to the wide range in photon energies of the radioisotopes used in nuclear medicine procedures and the limited effectiveness of lead aprons in protecting against higher-energy photons, such as positron-emission tomography (PET) (31).

The proposed U.S. Nuclear Medicine Technologists Feasibility Study is an expansion of the USRT Study. As noted above, exposures to USRT members, who were certified much earlier in time, are likely to be very different from more recently certified technologists specializing in nuclear medicine. To the best of our knowledge, there are no other studies of health risks to workers exposed to higher-energy radiation, such as that experienced by nuclear medicine technologists.

**A.5 Impact on Small businesses or Other Small Entities**

 No small businesses will be involved in this study.

**A.6 Consequences of Collecting the Information Less Frequently**

This is a one-time information collection.

**A.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.

**A.8.1** **Comments in Response to the *Federal Register* Notice**

In compliance with 5 CFR 1320.8(d), a notice of proposed data collection was published in the Federal Register on March 28, 2016, Vol. 81 P. 17192. Comments were solicited on the proposed information collection. No comments were received.

**A.8.2 Efforts to Consult Outside Agency**

 This study is being conducted in collaboration with researchers in the Division of Environmental Health Sciences, School of Public Health, University of Minnesota (Bruce H. Alexander, PhD, Project Director; telephone 612-625-7934, email balex@umn.edu).

**A.9** **Explanation of Any Payment or Gift to Respondents**

Respondents will receive no payments or gifts.

**A.10 Assurance of Confidentiality Provided to Respondents**

All information will be kept private to the extent allowable under the law. The study was approved with stipulations by the National Cancer Institute Institution Review Board on 4/6/2016; final approval is pending review of responses to the stipulations by the SSIRB Chair and primary reviewer (**Attachment 5A**). The study was approved by the University of Minnesota IRB on 2/22/2016 **(Attachment 5B)**. It has been determined that the Privacy Act applies to this collection of information (**Attachment 6**). A Privacy Impact Assessment (PIA) form was submitted to the NCI Privacy Coordinator on 5/19/2016 (**Attachment 7**). 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, including participant name, date of birth, gender, email address, and places of employment.

The University of Minnesota will maintain the roster of nuclear medicine technologists eligible for the USNMT study as identified from the records of the ARRT and the NMTCB, and the information collected on the CAWI questionnaires. University study staff members are cognizant of the sensitive nature of the data and have proven their ability to provide secure management of such data, having maintained the same information on the USRT cohort of general radiologic technologists obtained from the American Registry of Radiologic Technologists (ARRT). SSS will receive the initial questionnaire responses. SSS will transfer all data to UMN after questionnaire administration is completed and permanently delete all copies from their files.

As noted above, the USNMT study will utilize a CAWI questionnaire. This data capture method allows for automatically skipping questions that are inapplicable, thus ensures greater accuracy of responses. Email addresses will be obtained from the ARRT and NMTCB rosters. The University of Minnesota will send an email inviting technologists to participate in the study. The email will include a description of the study, consent information, letters of support from the ARRT and NMTCB, and details about how to complete the study questionnaire, including the website link and a unique password). No hard copy questionnaires will be collected. All study records will be kept in locked files in locked study offices. Electronic data will be 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 files containing no personal identifiers will be delivered to NCI periodically and will be accessible only to a limited number of individuals in 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 internal or external 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) will be requested upon receipt of NCI Special Studies IRB approval.

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 NCI Contracting Officer Representative.

**A.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. Some of the questions are considered sensitive, including current and previous employer names and locations. This information will be used to obtain historical badge dose readings from commercial dosimetry providers. Badge readings are needed to estimate annual organ-specific radiation doses associated with performing nuclear medicine procedures to assess radiation-related disease risks.

Participants will be advised in the recruitment email **(Attachment 3A)** that their participation is completely voluntary and that they may refuse to respond to any or all questions without penalty. Follow-up recruitment emails (**Attachment 3B**) will be sent to non-responders after 3 weeks, 6 weeks, and 9 weeks, as needed. Consent information (**Attachment 4**) will be included in the emails. The consent information will be repeated at the beginning of the questionnaire (Attachment 1), and subjects will be asked to consent to participate in the study before they will be able to complete the questionnaire.

**A.12.1 Estimates of Annualized Burden Hours**

The number of nuclear medicine technologists eligible for the feasibility study (the sampling frame) includes approximately 25,000 individuals certified in nuclear medicine technology in 1980 or later who have available email addresses. A total of 1,500 technologists (the sample) will be selected for the feasibility study. The primary goals of the feasibility study are to identify the eligible population of nuclear medicine technologists, determine their range of occupational radiation doses, and assess their response rate to a computer-assisted web interview. Those eligible for the feasibility study are relatively evenly distributed by sex, year of birth, and year certified, but not by type of certification. Technologists certified in positron-emission tomography (PET) are of greatest interest for the proposed expanded study of radiation-related disease risks in nuclear medicine technologists because they likely have the highest occupational radiation exposures; however, PET-certified technologists represent only about 4% of the eligible population. We plan to oversample from among PET-certified technologists to ensure that there will a sufficient number of participants from this group to get an accurate idea of their likely exposures. We will randomly select 250 technologists from among those certified in PET and randomly select the remaining 1,250 technologists from among those certified in all other nuclear medicine specialties. Since this will be our first experience using a computer-assisted web interview and in surveying a group of relatively young individuals, we are not sure what percentage of subjects will complete the questionnaire. Based on our previous experience from surveying a much older group of radiologic technologists four times between 1983 and 2013, where mail questionnaire response rates ranged from 78% (first survey) to 62% (fourth survey), with even greater declines in participation among the youngest cohort members, we estimate that about 50% of the sample of 1,500 will complete the feasibility study questionnaire.

The estimated time to complete the questionnaire is 30 minutes. Over the course of three years of information collection, it is anticipated that there will be 750 respondents (50% of the sample) which will amount to 375 burden hours. The annualized total burden hours are 125 for 250 respondents.

|  |
| --- |
| **Table A.12-1. Estimated Annualized Burden Hours** |
| **Type of Respondent** | **Instrument** | **Number of Respondents** | **Frequency of Response** | **Average Time per Response****(Hours)** | **Annual Hour Burden** |
| Nuclear Medicine Technologists | Nuclear Medicine Questionnaire | 250 | 1 | 30/60 | 125 |
| **TOTAL**  | 250 | 250 |  | 125 |

**A.12.2** **Annualized Cost to Respondents**

The estimated annual burden cost is $4,500 (Table A.12-2) and over a three-year information collection period approximately $13,500. This was calculated using data based on a 2016 survey of Certified Compensation Professionals at thousands of Human Resource departments in U.S. companies of all sizes and industries, for people with the title

Nuclear Medicine Technologist, the median annual salary is $75,309 and the median hourly wage is $36.00 (<http://www1.salary.com/Nuclear-Medicine-Technologist-Salaries.html>). There will be no direct costs to the respondents other than their time to complete the questionnaires or to retrieve employment information.

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| --- |
| **Table A.12-2. Annualized Cost to Respondents** |
| **Type of Respondent** | **Annual Hour Burden** | **Wage Rate** | **Total** |
| Nuclear Medicine Technologists | 125 | $36.00 | $4,500 |
| **TOTAL COST** | 125 |  | $4,500 |

**A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers**

No additional cost burden to respondents and record keepers is anticipated. There are no capital, operating, or maintenance costs to report.

**A.14 Annualized Cost to the Federal Government**

The annual cost to the government is $94,903.Over the three-year period for which OMB approval is being requested, annual contract costs include $49,462 to the University of Minnesota to coordinate the study and $23,110 to Social & Scientific Systems, Inc. to develop and maintain the computer-assisted questionnaire. The annual cost for NCI intramural staff is $21,831. These figures include the costs of study design, subject tracing, data collection, analysis, and report writing.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/****Step** | **Salary** | **% of Effort** | **Fringe Rate** | **Total Cost to Government** |
| **Federal Oversight** |  |  |  |  |  |
|  Principal Investigator | AD 00 | 101,500 |  5 |  | 5,075 |
|  Senior Investigator | AD 00 | 273,709 | 2 |  | 5,470 |
|  Staff Scientist | AD 00 | 128,385 | 2 |  | 5,136 |
|  Dosimetrist | AD 00 | 112,393 | 2 |  | 4,496 |
|  Statistician | AD 00 | 165,360 | 1 |  | 1,654 |
|  **Sub-Total** |  |  |  |  | **21,831** |
|  |  |  |  |  |  |
| **Travel** |  |  |  |  | **500** |
|  |  |  |  |  |  |
| **Contractor Costs** |  |  |  |  |  |
|  **University of Minnesota** |  |  |  |  |  |
|  Principal Investigator |  | 183,290 | 0.005 | 0.337 | 1,225 |
|  Study Manager |  | 90,917 | 0.020 | 0.337 | 2,431 |
|  Study Coordinator |  | 73,320 | 0.225 | 0.337 | 22,056 |
|  Data Analyst |  | 67,122 | 0.040 | 0.337 | 3,590 |
| Interview Specialist |  | 45,828 | 0.015 | 0.079 | 742 |
|  Student Workers |  | 20,904 | 0.075 | 0.000 | 1,568 |
|  Other Direct |  |  |  |  | 929 |
|  G&A (52%) |  |  |  |  | 16,921 |
|  **Sub-total** |  |  |  |  | **49,462** |
|  |  |  |  |  |  |
|  **Social & Scientific Systems** |  |  |  |  |  |
|  Study Manager |  | 91,500 | 0.030 | 0 | 2,745 |
|  Data Manager |  | 75,800 | 0.040 | 0 | 3,032 |
|  Data Analyst |  | 58,900 | 0.040 | 0 | 2,356 |
|  Research Associate |  | 54,200 | 0.010 | 0 | 542 |
|  Questionnaire Design |  | 45,500 | 0.050 | **0** | 2,275 |
|  G&A (102%) |  |  |  |  |  |
|  Fee |  |  |  |  | 991 |
|  **Sub-Total** |  |  |  |  | **23,110** |
|  |  |  |  |  |  |
| **Other Costs** |  |  |  |  | **0** |
|  |  |  |  |  |  |
| **TOTAL** |  |  |  |  | **94,903** |

**A.15 Explanation for Program Changes or Adjustments**

This is a reinstatement with change. The proposed changes have resulted in a decrease in the estimated annual number of respondents from 37,053 general radiologic technologists in the USRT cohort (21,700 to the fourth survey general questionnaire, 7,000 to the radioisotope (nuclear medicine) procedures questionnaire, 6,300 to the fluoroscopically-guided procedures questionnaire, and 2,053 medical records clerks) to an estimated 250 annual respondents (to the revised nuclear medicine procedures questionnaire only) among a sample of 1,500 nuclear medicine technologists targeted. This reflects a shift in focus from assessing radiation-related cancer and other disease risks in general radiologic technologists certified during 1926-1980 to evaluating the feasibility of conducting a cohort study of radiation-related disease risks in nuclear medicine technologists certified after 1980.

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

Data from this information collection will be used to (a) characterize patterns in nuclear medicine procedures performed, related work and safety practices, and badge dose measurements over time, and (b) describe correlations between work history factors and objective measures of cumulative radiation exposure in certified nuclear medicine technologists in the U.S. At least two manuscripts covering these topics will be published.

A projected time schedule for the U.S. Nuclear Medicine Technologists Feasibility Study described in Section A.6 is displayed in Table A.17-1. All times are after initial OMB approval for the Nuclear Medicine Procedures Questionnaire.

|  |
| --- |
| **Table A.16. PROJECT SCHEDULE** |
| **Component** | **Months** |
| Information collection | 0-30  |
| Commercial dosimetry linkage  | 12-24 |
| Data analysis | 24-34 |
| Manuscript preparation | 30-36 |
| Submit first publication | 36 |

**A.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.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification