Supporting Statement

Study to Improve Thyroid Doses from Fallout Exposure in Kazakhstan

Submitted by

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October 5, 2007

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Radiation Epidemiology Branch (REB), Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI), of the National Institutes of Health (NIH) is authorized under the Public Health Service Act, Section 411, [42 USC 285a] to collect information to investigate (or test) hypotheses concerning environmental and host determinants of cancer. It is the mandate of the 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. The REB mission is to characterize and quantify cancer risks associated with different types of radiation exposure, improve dosimetry, elucidate biological mechanisms of radiation carcinogenesis, and study factors that may modify the carcinogenic effects of radiation exposure.

This petition is for approval of a new data collection entitled **'**Study to Improve Thyroid Doses from Fallout Exposure in Kazakhstan**'.** This field work builds on an existing study of thyroid disease among individuals in Kazakhstan exposed during childhood to radioactive fallout from nuclear tests conducted at the Semipalatinsk Nuclear Test Site (SNTS) between 1949 and 1962. In 1998, NCI collaborated with the Semipalatinsk State Medical Academy (SSMA) and the Kazakh Research Institute for Radiation and Medical Ecology (IRME) to conduct a field study to determine prevalence of thyroid disease in relation to fallout radiation exposures from these nuclear tests. About 3,000 residents in eight villages in Kazakhstan were screened to identify thyroid disease, and thyroid nodules were diagnosed in 917 subjects by follow-up fine needle aspiration biopsy and cytopathology. These eight villages differed in ethnic makeup, with 3 that were over 95% Kazakh and five primarily Russian with varying proportions of ethnic

Kazakhs. Fallout levels were known to vary substantially by village, but existing estimates for doses from external and internal (mainly ingested) radiation sources in fallout were problematic. At screening, subjects were asked about their dietary histories to help with dose reconstruction through the pasture-milk exposure pathway. Another source of information is an unpublished summary evaluation of dietary practices among villagers in the region, provided by the Kazakh Research Institute for Radiation and Medial Ecology (IRME)

Subsequently, NCI investigators, collaborating with U.S. and Russian dosimetry experts on nuclear testing programs in each country, developed a highly sophisticated dose reconstruction methodology applicable to this population, which is state-of-the-art for fallout deposition. Thus, we feel that our current information about the amounts and types of radioactive fallout affecting villages in which our subjects were living during the period of testing is adequate. However, we do require additional information about factors, mainly behavioral and cultural, that influence how much of the deposited radioactivity was transferred to the thyroid glands of individual subjects. These factors include shielding from external radiation sources provided by buildings (construction materials and time typically spent outdoors) and pathways by which radioactive iodine in fallout may have been transferred by ingestion to individual subjects (amounts of milk consumed from different types of dairy animals grazing on contaminated pastures).

Ethnicity, geographic location, age, and gender are all related in various ways to the modifying factors discussed, and we propose to clarify those relationships. For example, adobe construction, which shields out 12/13 of ambient gamma-ray radiation, is characteristic of the predominantly Kazakh villages to the south and southwest of the test site, where timber is scarce, whereas timber (log) construction, which shields out only 2/3 of this radiation, is typical of the predominantly Russian villages to the northeast where timber is relatively plentiful. Did ethnic

Kazakhs who were living in predominantly Russian villages tend to have adobe or log houses? How did time spent outdoors, unshielded by buildings, vary by age and gender? Cows, horses, sheep, and goats are dairy animals that differ greatly with respect to concentration of dietary iodine in milk. What was the relative importance of these animal sources of milk in children's diets, and how did it vary by location, ethnicity, age and gender, and within groups defined by these variables? How much milk was consumed at different ages, and how much variation was there for various reasons, including economic status? We are interested in estimates of these factors and, especially, in quantifying the uncertainty of such estimates.

We feel that a directed discussion, among women who cared for children at some time during the testing period, will provide additional information about the availability of milk from different sources and its consumption by children at the time, as well as more general summary information about amounts of time children spent outdoors, when they would be unshielded by buildings. Similarly, focus groups of men who cared for family cows, goats, horses, and sheep will provide information on pasturing and supplemental feeding practices for dairy animals used by individual families as opposed to collective enterprises which reportedly delivered milk to government agencies

Analyses of data using preliminary dose estimates based on the estimates of deposited radioactivity mentioned above and available information from the initial screening questionnaire and from the IRME dietary summary indicates that internal and external radiation exposures independently and significantly contributed to the dose response for thyroid nodules. This analysis did not take into account the uncertainty structure of the individual dose estimates, and a major goal of the proposed sub-study is to provide information that can be used to quantify the uncertainty associated with informed estimates of the modifying factors outlined above, in addition to the available uncertainties associated with estimates of fallout deposition. Based on a

large and increasing statistical literature, it is unlikely that the statistical significance of our risk estimates will be affected by revising major assumptions and by quantifying and accounting for uncertainty. However, the point estimates of the two dose effects, and their ratio, which is a measure of the relative effectiveness of the two types of radiation exposure, may change and it is important that the final values represent the best information that we can obtain.

With this submission, the NIH Office of Communications and Public Liaison (OCPL), seeks to obtain OMB's approval to collect information from approximately 32 men and 96 women who were adult residents of four villages near the Semipalatinsk Nuclear Test Site (SNTS) in Kazakhstan to improve on published dose estimates received by individuals, especially children, exposed to nuclear fallout (Gordeev et al., 2006 [6], Gordeev et al., 2006 [5]). The four villages were selected from among the eight villages participating in the 1998 screening study to represent a range of moderate to high fallout exposure levels. Two of the villages are predominantly Russian and are representative of the five villages to the northeast of the test site, affected mainly by the first Soviet test, in August, 1949, and the other two, south and southeast of the test site, are representative of the three predominantly Kazakh villages affected mainly by the tests of September 24, 1951 and August 12, 1953. These three tests are considered to have contributed about 90% of all the radiation exposures to persons living near the STS. We are also interested in discriminating between ethnicity per se and location (the relatively well-watered northeast region cf. the more arid regions to the south and southeast of the test site) as determinants of factors that might modify external and internal doses.

Groups of approximately 8 men each in the four villages will be asked about construction materials used in houses and schools, types of dairy animals from which milk was obtained, and pasturing and feeding practices (Appendix A). Some exposures to nuclear fallout were from tests conducted during periods when school was in session and others occurred when school was

not in session. Three different groups of approximately 8 women each in the four villages will be asked about types and amounts of milk and milk products consumed by children, by participants, and the amount of time children spent outdoors during periods when school was in session (Appendix B) or when school was not in session (Appendix C), as applicable to the specific village. At the conclusion of each focus group, all participants will be asked to complete a brief evaluation form indicating the extent of their agreement with six statements about the focus session (Appendix D).

Multiple nuclear tests were conducted at the SNTS during 1949-1962. Village residents near the test site received high doses of internal and external radiation to the thyroid gland (up to 10 Gy for internal and 0.6 Gy for external radiation) as a result of the nuclear tests. Internal radiation exposure occurred primarily through consumption of milk and other dairy products from animals grazing on pastures contaminated with radioactive iodine. The external dose received by individuals was a function of the exposure rate when the fallout was deposited, shielding provided by buildings and the number of hours spent outdoors on a daily basis. Improved thyroid dose estimates for individuals exposed as children are of special interest since (1) thyroid radiation doses are strongly related to the consumption of milk contaminated with radioactive iodine; (2) thyroid doses are inversely related to thyroid mass and thus higher in children; and (3) the thyroid glands of children are particularly vulnerable to the tumorogenic action of radiation (Mushkacheva et al., 2006 [19]).

A preliminary dose assessment was completed in 2005 (Gordeev et al., 2006 [6], Gordeev et al., 2006 [5]); however, incomplete information on several critical factors that affected the relationship between deposited radioactivity and human exposure led to wide uncertainties in the estimated doses. Dose estimates could be improved considerably with collection of data from women and men who were adult residents of the exposed villages at the time of the nuclear tests.

We will recruit women who were over 70 years of age who had children or provided care to children during the 1950's and men who were also age 70 or older and who were engaged in farming and care of dairy animals at the time of the nuclear test. The main reason for asking mothers or those who provide care to children is that they should have better knowledge of milk consumption and activities of children than that recalled decades later by the children themselves. The subjects will be identified from village and regional records screened by study staff for eligibility, and ability and willingness to participate in focus group interviews. Using focus group interviews, the NCI investigators will collect retrospective information about factors influencing radiation dose to the thyroid gland in children of two distinct ethnic groups: Kazakhs and typically descendants of Russian farmers. These factors include milk and milk product consumption, distribution of time spent indoors and outdoors, radiation shielding provided by dwellings and other buildings, seasonal practices of pasturing and supplemental feeding of dairy animals for the months following the nuclear tests, and a temporary evacuation from two villages prior to the first Soviet H-bomb test in August, 1953. The conditions of fallout exposure in Kazakhstan are similar to what would be expected from a hypothetical nuclear accident or radiation terrorism involving high levels of local fallout and are, therefore, of significant public health interest.

The focus group methodology was selected primarily because of the anticipated difficulty in long-term recall needed in obtaining information desired. Previous research indicates that focus groups may stimulate in-depth individual participant responses more than individual interviews (Edmonds, 2005 [2]). Participant interaction is a unique and compelling feature of focus groups (Kitzinger, 1995 [9], Twinn, 1998 [25], Lakshman et al., 2000 [13], Mclafferty, 2004 [15], Rabiee, 2004 [21], Edmonds, 2005 [2])where participants share their experiences to describe the range of experiences in a group as well as the reasons for differences among

participants. This feature is particularly useful for Kazakh residents because individuals in these villages know each other very well and cared for each other's children. We will also employ several additional methods to prompt long-term recall in the focus group sessions, including visual aids (e.g., drinking bowls typically used at the time for recalling the quantity and volume of milk consumed, and wall charts designed to lead participants through a typical day in recalling activities in relation to meals and other typical daily activities), and observation of focus group interviews and debriefing sessions with the focus group facilitators for evaluating the utility of discussion prompts in aiding recall.

Nevertheless, it is inevitable that recall information from the focus group interviews on activities and behaviors of some fifty years ago will have limitations and potential bias. Although data obtained from selected focus group subjects may not be generalized to larger populations (Merton et al., 1990 [16], Morgan and Krueger, 1998 [17], Edmonds, 2005 [2]), there may be occasions, as in our situations, when it is the only reasonable alternative to conducting a large-scale field study. There are very few people who have personal knowledge of daily life practices in rural Kazakhstan villages in the 1950s. The screening process proposed for focus group participants will restrict subjects to men and women who lived in the village at the time and who were of age to have personal experience with dairy consumption and daily life practices at the time of the tests. Because there are so few of these individuals remaining in the villages, we anticipate that eligible focus group participants may in fact represent the entire population of surviving parents of children during the time of the tests. However, participants available for the current focus group study may have had different daily life practices in the 1950s than parents of 1998 cohort members. There is no way to completely discount this potential bias but questions were designed to ask about their own life practices and follow-up probes asked if their experience was different for others in the village they knew. When possible, multiple groups will

be conducted among selected participant groups to serve as a validation from one group to the other and identify any biases that may exist. There is also the potential that village residents with more resources have moved out of the village either to another village or to Semipalatinsk (the closest city). However, it is our understanding that there was generally minimal variability of resources among village residents in the 1950s and that most village residents lived in poor conditions.

The focus group interviews are designed to elicit both individual- and group level data to capture the extent of variability among individuals and groups. Most of the questions in the women's guide will elicit responses from each individual participant. Each individual participant will be asked to report on her children's consumption of milk and milk products. The group level questions pertain to village-level practices such as whether boys and girls or Kazakhs and Russians differed in their consumption. The question of time spent indoors will also be asked at the group level so as to reduce the time burden on the individual participants. For those questions which seek group response, we will try to obtain responses from multiple participants and not merely defer to the few who answer most definitively.

The study of Kazakhstan residents is based on the unique situation where a population was actually exposed to nuclear weapons fallout (rather than any surrogate radiation) - a situation of great security interest today. The Kazakhstan population's exposures include external doses and internal doses through contaminated dairy products, and the same exposure pathways exist in the U.S. today (and elsewhere). Better understanding of those pathways is useful, particularly as national authorities develop strategies to avert dose and mitigate food contamination from radiologic devices. The lack of precision on individual doses in the Kazakhstan study, as acknowledged above, is a problem shared in virtually every environmental dose reconstruction, but should not prohibit improving our understanding on specific issues including: the effects of

location and distance from a detonation site on resulting doses, the contributions of short-lived iodines to the total dose (also dependent on time and location), the effects of dairy management practices, and the effects of varying lifestyles. The lifestyle in Kazakhstan villages in the 1950s was based on very limited economic opportunities, an extremely limited variety of foods, and limited variations in farming practices, and therefore individual intakes in Kazakhstan may have been much less variable than in U.S. situations where lifestyles can be extremely variable. This provides another justification for the present focus group approach. Few if any, epidemiologic studies conducted to-date have had sufficient precision and statistical power to 'alter current scientific understanding of biological effectiveness of internal and external radiation exposures' on their own. The Kazakhstan study, however, has the opportunity to contribute to what is presently only a very limited understanding on the relative biological effectiveness of internal and external radiation exposures from nuclear weapons fallout radiation, as briefly reviewed below, and more generally to broadening our experience and understanding in estimating doses from environmental exposure to weapons fallout.

Currently, our understanding of risks from external compared to internal dose is based on insufficient information from few studies (Gilbert et al., 2002 [4]): studies in Utah relative to fallout from the Nevada test site, which were, in general, of insufficient power to make definitive conclusions, and studies of Marshall Islanders, which are highly uncertain due to lack of good data on contamination levels immediately following the tests, a poor understanding of intake pathways for Marshallese, and a complex mixture of short- and moderately-long lived isotopes. Because the dose and related health risk data are so sparse and uncertain, our present understanding on the relative significance of external exposure versus internal dose due to radioiodine isotopes is primarily based on an extrapolation from other less relevant studies, e.g., releases from the Hanford nuclear site (where doses were also very uncertain, the study only had

moderate statistical power, and there many dissimilarities to nuclear weapons fallout since the Hanford emissions were all gaseous), and medical administrations of ^{131}I (primarily to adults). Thus, the Kazakhstan study has the opportunity to contribute to, though not necessarily to solve, our limited understanding on the likely doses possible from exposure to radioactive fallout, the related health risks per unit dose (with particular reference to children) and may, in fact, contribute to better understanding the relative risk from external and internal exposure.

2. Purpose and Use of Information Collection

The proposed study is a dose reconstruction effort aimed at lifestyle and other factors influencing the relationship between deposited radioactivity and radiation dose to the thyroid glands of children and adolescents living in particular villages in Kazakhstan during the period of above-ground nuclear testing at the STS. The objective is to model thyroid dose as an uncertain function, over time, of the estimated remaining radioactivity in the fallout deposited on the ground at specific locations, estimated shielding against external radiation sources provided by buildings, and estimated uptake of available radioactive iodine through consumption of milk from dairy animals grazing on contaminated pasture. The shielding and milk consumption factors will be modeled as uncertain functions of age, gender, location (the northeastern region or the more arid southern and southeastern regions), season of the year, and ethnicity (Kazakh or Russian). Because the tests that contributed the bulk of fallout activity to the study population occurred in August and September and 131-I has a radioactive half-life of 8 days, the investigation will focus on outdoor activity and milk consumption during the months of August-November.

To obtain the necessary data, NCI proposes to use the focus group interview data collection method, which is well-suited to the population under study (Morgan, 1997 [18], Krueger and Casey, 2000 [11], Stewart et al., 2006 [23]). The resulting models will be applied to

the entire study population, i.e., to some 3000 subjects screened in the eight villages during in the 1998 field investigation. The final dose estimates will be used to further understanding of thyroid disease risks following internal and external radiation exposures, including a comparison of the biological effectiveness of radiation doses from internal compared to external exposures.

Ultimately, individual doses based on the modeled doses will be fitted to existing nodule prevalence data. The dose response analysis will specifically take into account the estimated uncertainty structure of the resulting individual dose estimates. The assumed error structure should combine both classical and Berkson error for individual doses corresponding to modeled estimates. We will not assume that individuals with the same predictor values (age, sex, ethnicity, etc.) are identical, but will postulate an informed subjective within-group uncertainty distribution which will be an important component of the analysis.

At present, our main finding based on preliminary dose estimates shows that nodule prevalence is significantly and independently associated with estimated doses from external and internal radiation sources. This dependence was found to persist in crude sensitivity analyses in which all external and/or internal doses for subjects screened in a single village were halved or doubled, although the numerical values of the radiation-specific coefficients were affected. Such systematic variation in doses might occur if deposition of fallout on a village were grossly overestimated or underestimated, or if dependence on milk from animals that efficiently transfer dietary iodine, like goats, sheep and to a lesser extent horses, were erroneously assessed. It seems likely, from a number of methodological papers in the literature, that formal consideration of dosimetric uncertainty may change the ERR/Gy estimates for external and internal dose, but not their statistical significance.

Collection from small focus groups of persons who were young adults at the time of the nuclear tests will focus on specific information about children's milk consumption and time

spent indoors and outdoors, radiation shielding, and pasturing and feeding of dairy animals for the months following the nuclear tests will allow investigators to evaluate and change, as appropriate, the assumptions and input values for the parameters used in the dose estimation model. The new data should result in a more informed characterization of uncertainty. In addition to improving estimated internal and external doses and better characterizing the uncertainty distributions for the Kazakhstan study group, the collected data will be directly relevant for improving estimated radiation doses to the thyroid in a parallel NCI study entitled "Study of Thyroid and Thyroid Disease among individuals who were Children at the time of the Chornobyl Accident" (Clinical Exemption No. CE 00-10-02).

Currently, NCI dosimetrists and their colleagues in Russia and Kazakhstan have estimates of activity deposited on the ground and time of deposition for different locations along the fallout trace, but only minimal and uncertain information about shielding provided by buildings, childhood milk consumption, and time spent outdoors. External dose was estimated from these factors, and specified uncertainties were applied to yield a cumulative dose with an uncertainty distribution (Gordeev et al., 2006 [5]). Data collected from the focus groups of individuals who were adults at the time of the nuclear tests may change appreciably the current input values (and their uncertainties) for milk and milk products consumed by children at the time of the testing, their time spent outdoors, and shielding.

Internal dose was estimated as a function of age at exposure, measurements of fallout deposition, and assumptions about pastures used by dairy animals, amount of (contaminated) vegetation consumed by different types of grazing animals, amount and types of supplemental feed (stored fodder), species-specific transfer of radioiodines to milk, and amounts of species-specific milk and milk products consumed over time following fallout deposition (Gordeev et al., 2006 [6]). Information collected from the focus groups could impact all of these factors.

3. Use of Improved Information Technology and Burden Reduction

The primary method for collecting information from participants will be through focus group interviews guided by a moderator (see Appendix A-C), with two assistants. Every effort has been made to minimize the length of the focus group session and to format the questions in a manner that would optimize clarity and minimize the burden on the respondent. The moderator will lead the discussion using detailed probes to help stimulate participant memory. Wall charts will be used to assist participants in recalling information and to collate specific data (see Appendix A-C). One assistant will take notes on a computer laptop using a template designed to collect the data sought and the other assistant will record information on the wall charts. Participants will not be required to provide written responses to focus group questions. At the end of the session, they will be asked to evaluate the focus group session by checking boxes for their level of agreement with six statements about the session. No personal identifiers will be retained.

Audio recordings of the focus group session will be made and used to generate transcripts; this will improve the reliability (reproducibility of analysis results from the recording) of the data (Khan et al., 1991 [7]). Transcripts of the focus group data will be prepared and translated into English following the completion of the fieldwork. The transcripts from the sessions will be compared to the notes taken by the moderator's assistant to ensure that the data provided by the participants were recorded correctly in the notes. To maintain confidentiality during the audio taping, each participant will be identified by a first name only or a nickname by the focus group moderator. No personal identifiers will be recorded in the notes.

4. Efforts to Identify Duplication and Use of Similar Information

The population in Kazakhstan is one of few populations in which environmental releases of radioactive materials into the atmosphere have resulted in substantial internal and external thyroid radiation doses. The other populations include people exposed to fallout from the Nevada Test Site (Lyon et al., 2006 [14]) and the Chornobyl reactor accident (Bogdanova et al., 2006 [1]), and to atmospheric releases from the Hanford (Kopecky et al., 2005 [10]) and Mayak plutonium facilities (Mushkacheva et al., 2006 [19]) in the US and USSR, respectively. The Kazakhstan population is unique among these populations in several respects: (1) levels of ground deposition were much higher than those experienced by populations exposed to fallout radiation from the Nevada Test Site or to atmospheric releases from weapons manufacturing at the Hanford and Mayak plutonium facilities; (2) among large populations with high environmental releases of radioactive materials, the Kazakhstan population is second in size only to the residents of Belarus, Ukraine, and Russia most heavily exposed to radioactive materials released during the Chornobyl reactor accident; and (3) unlike the Chornobyl population, the Kazakhstan population was exposed to high levels of radiation from external as well as internal sources. The ability to evaluate the RBE for external and internal radiation exposures, in terms of thyroid disease risk, within a single population is a distinct advantage over comparing risks from different groups, such as the populations exposed internally from the Chornobyl accident and those exposed externally from the Hiroshima and Nagasaki A-bombs, which have different background levels of thyroid disease and may have differential exposure to non-radiation risk factors.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Frequency of Data Collection

This is a one-time data collection of information about sources and amounts of milk and milk products consumed, pasturing and feeding of dairy animals, and construction materials used in houses and schools from approximately 128 men and women who resided near the SNTS during nuclear tests conducted in the 1950s. The consequence of not collecting these data is that NCI dosimetrists will not be able to improve on published estimates of internal and external radiation doses for individuals exposed to radioactive fallout from nuclear weapons tests at the SNTS in Kazakhstan during 1949-1962.

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 Federal Register Notice and Efforts to Consult Outside the Agency

A notice for public comments on the proposed data collection activities required by 5 CFR 1320.8(d) was published in the *Federal Register* on Thursday, January 18, 2007 (Volume 72, Number 11, pages 2286-2287). Comments were solicited. No public comments were received.

NCI investigators met with the Deputy Director from the Institute of Nutrition in Almaty, Kazakhstan, Dr. Igor Tsoy (tsoi_igor@mail.ru; +7-3272 422 704), in 2005 and conducted an extensive literature review of both English and Russian language publications in an attempt to find dietary surveys from the period of the nuclear tests. During summer 2006, the primary

collaborator, Dr. Zhaxibay Zhumadilov (zzhuma@mail.ru; +7 322 256 1604) in Kazakhstan, interviewed archive directors and local agricultural experts in an attempt to answer questions about the numbers of animals kept by the village and by individual households, grazing locations of dairy animals and supplemental feed given to dairy animals. NCI investigators also met with Dr. Boris Ivanovich Gusev (nii_rm@relcom.kz; +7 322 264 5649) in 2005 at Kazakhstan Institute for Radiation and Medical Ecology (IRME) a long-time collaborator of the NCI Radiation Epidemiology Branch. He is a very important figure in the studies of exposure to radioactive fallout from the Semipalatinsk State Nuclear Test Site as he established an initial cohort of people in the 1960s. He was the director of Dispensary Number 4, the facility tasked with monitoring the health effects of the nuclear tests in the villages. In 2005, NCI investigators met with Deborah Mennuti (Mennutid@state.gov; +7 (3272) 50-76-12), Chief of Political and Economic Affairs at the U.S. Embassy in Almaty, Kazakhstan. The purpose of the visit was to explain the study and provide an overview of the procedures. The Embassy does not have any direct role in Semipalatinsk but is very interested in scientific and humanitarian aid work going on in the region.

9. Provision of Payments or Gifts to Respondents

For this focus group effort, we plan to give each participant the equivalent of $5.00 in local currency, as a small token of our appreciation for their participation. A small gift is customary in the Kazakhstan culture when requesting assistance.

10. Assurance of Confidentiality Provided to Respondents

This study is supported by Contract NO1-CP-31013 with Research Triangle Institute (RTI), entitled "Studies of Radiation and Cancer Risk". The SSMA is a subcontractor to RTI.

Research involving human subjects conducted by RTI is covered under Assurance of Compliance number FWA3331. This study has been reviewed and approved by the Institutional Review Boards at RTI (protocol number 11746) and SSMA (KN2-434-a) and is currently under review at the NCI (approved with minor stipulations; a final copy will be provided when available) (Appendix E).

Focus group participants will be selected and recruited by researchers at the SSMA. SSMA will maintain a list of study participants that contains only personal identifiers (name, village, year of birth, and gender) in accordance with NCI and RTI requirements, i.e. all data will be stored in password-protected computers and locked cabinets in secure study areas and will be accessible only to staff working specifically on this project. NCI and RTI personnel will not have access to the list of study participants as described above. At the start of each focus group, the moderator will read the consent form to participants, respond to any questions, and ask each person to sign to indicate their consent to participate (Appendix F). Focus group participants will be asked to maintain the confidentiality of their peers in the focus group. No personal identifiers will be recorded in any notes taken by the moderator or her assistants. To maintain confidentiality during the audio taping, each participant will be identified by a first name only or a nickname given by the focus group moderator. Audio recording of the sessions will begin only after participants have introduced themselves to the group. All records and recordings of focus group responses will be stored without personal identifiers and without the potential to link to personal identifiers. SSMA personnel will receive only anonymized focus group response data, thus, it will not be possible for them to link the information back to specific individuals. Audiotapes will be destroyed at the conclusion of the study.

11. Justification for Sensitive Questions

NCI investigators will not be asking any questions that are considered to be of a sensitive nature. The questions NCI will be asking are about building materials of houses and other structures, sources of dairy products, pasturing and feeding of dairy animals, and types and amounts of milk and other dairy products consumed during the time of the nuclear tests in Semipalatinsk, Kazakhstan in the 1950s.

12. Estimates of Hour Burden for Information Collection

The participant burden for this data collection is estimated to be approximately 2 hours for the focus group (1 hour and 55 minutes) and post-focus group evaluation (5 minutes). This estimate is shown in Table 1. Note (CL): I presume that this table will be easier to read after it is given more room

Table 1 – Estimates of Annualized Hour Burden to Respondents

Type of Respondent	Number of Respondents	Frequency of Response	Average Hours Per Response	Total Hours (3 yr)	Annual Hour Burden
Focus group					
Kazakhstan villagers (adults ≥ 70 yrs old)	128	1	1.9	243	81.1
Post-focus group evaluation					
Kazakhstan villagers (adults ≥ 70 yrs old)	128	1	0.1	13	4.3
Total	**128**	**1**	**2.0**	**256**	**85.3**

NCI investigators estimate the cost to respondents to be $3.13 per hour for these focus group interviews. Kazakhstan has a per capita income of $9,100, or about $25 per day or approximately $3.13 per hour. The total estimated cost to respondents over three years is $801 (see Table 2). There will be no direct costs to the respondents other than their time to participate in the focus group and complete the brief evaluation.

Table 2 – Estimates of Annualized Cost to Respondents						
Type of Respondent	**Number of Respondents**	**Frequency of Response**	**Average Hours Per Response**	**Average Hourly Wage**	**Total Cost (3 years)**	**Annual Cost**
Focus group						
Kazakhstan villagers (adults ≥70 years old)	128	1	1.9	$3.13	$761	$253
Post-focus group evaluation						
Kazakhstan villagers (adults ≥70 years old)	128	1	0.1	$3.13	$40	$14
Total	**128**	**1**	**2.0**	**$3.13**	**$801**	**$267**

13. Estimates of Total Annual Cost Burden to Respondents or 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

Two types of government costs will be incurred including government personnel, and contracted data collection costs. The projected total cost of this project is **$207,904.** Table 3 shows the salary, expenses and contract costs to complete this information collection. These figures include the costs for study design, development of study materials, focus group member enrollment, data collection, incentive, language translations, data processing, dosimetry model updates, statistical analyses, and report writing.

Table 3 – Annualized Cost to the Federal Government (in US dollars)		
	Total (3 yr)	**Annual**
Government Costs for Salaries and Expenses	**18,500**	**6,167**
Contract Costs		
Main RTI contract	**101,404**	**33,801**
SSMA subcontract	**88,000**	**29,333**
Total	**$207,904**	**$69,301**

15. Explanation for Program Changes or Adjustments

Not applicable. This is new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This study is expected to continue for approximately three years, including development of study materials and procedures, identification and enrollment of focus group members, an initial pilot study of data collection instruments, collection of data from focus groups, incorporation of collected data into the dose assessment models, dose-response analyses, and preparation and publication of manuscripts. Thus, a three-year OMB clearance is requested. A projected time schedule for this study is displayed in Table 4. All times are after initial OMB approval is received.

Table 4 – Project Schedule	
Recruit focus group members	0-1 month
Conduct focus group interviews	2-3 months
Transcribe focus group audiotapes and notes	4-7 months
Translate Kazakh transcripts into English	5-7 months
Translate Russian transcripts into English	8-10 months
Develop preliminary input variables for dose assessment	10-12 months
Incorporate new variables into dose assessment models and recalculate internal and external doses	12-18 months
Incorporate uncertainties in dose estimation	15-21 months
Conduct follow-back to study participants for clarifications, as needed	4-24 months
Conduct dose-response risk analyses with and without adjustment for uncertainty	24-30 months
Prepare and submit manuscripts on dose assessment and dose-response	30-36 months

Transcripts of the focus group data will be prepared and translated into English following the completion of the fieldwork. The transcripts can be used in conjunction with the charts completed by the groups to summarize the focus group data and prepare it for calculating internal and external radiation dose and subsequently the dose-response analysis. Data collection is stratified by ethnicity, gender- and age- group. The following data summaries will be done

first by focus group and then combined at the village-level to generate a distribution of estimates. If the village-level ranges for a given item (e.g., fresh mare milk consumption by 1-3 year old Kazakh girls) are consistent between villages, then summary ranges for different age-, gender- and ethnicity- groups will be generated using data from across the focus groups.

Milk and dairy consumption patterns: The focus group will generate an estimate of the number of servings per week (frequency) and amount of milk consumed per serving (typical quantity) for each milk type for each age, sex and ethnic group. The NCI investigators will use these estimates to calculate the weekly consumption rates for each age, sex and ethnic group (e.g., 7-11 year-old Kazakh girls, 1-3 year-old Russian boys). The variability of individual consumption rates around the typical values also will be estimated.

Agricultural practices: For each milk type, NCI investigators will summarize the milk availability and preparation data as follows, and evaluate whether these data vary by ethnic group and village.

- Availability (yes or no) at the time of the nuclear tests and during the following two months
- Source (yes or no) for each of the following from which milk was obtained: own animals, neighbors, stores, outside the village
- Time (days) between milking and consumption for local (in village) milk
- Time (days) between milking and consumption for milk brought in from outside the village
- Maximum duration of storage (days)
- Fermentation time (days) of sour milks
- Typical storage time (days) of sour milks after fermentation

For each animal, NCI investigators will summarize the feeding and grazing information from each village as follows:

- Distance (km) and direction of pastures from the village

- Amount of each type of supplemental feed
- Percent of pasture covered by snow at the time of the test and during the next two months

Outdoor activity: The estimates of the outdoor activity will be summarized as follows: For each age, gender, and ethnic group, the focus group will generate an estimate of the typical amount of time (hours) spent outdoors with separate estimates for the summer and school months. The variability of individual values around the typical amounts of time spent outdoors also will be estimated**.**

Construction materials of residences and schools: From each focus group, NCI investigators will obtain the estimated percent of Russians and Kazakhs living in each type of house, wooden and **adobe.**

Analysis and Publication: Analyses and manuscripts focusing on dose assessment and thyroid disease radiation dose-response will be led by NCI researchers. Basic dose-response analyses will be conducted using the GMBO algorithm of the Epicure software package to analyze binary outcome data (Preston et al., 1993 [20]). Maximum likelihood methods will be used to account for uncertainty in the estimated doses (Stram and Kopecky, 2003 [24]).

Public Audiences: The public audiences most interested in the project's findings are: radiation biologists and radiation epidemiologists; agencies responsible for establishing medical and occupational radiation exposure standards; agencies responsible for responding to environmental exposures from nuclear power or processing plants, or to acts of radiological terrorism; and individuals exposed to internal or external radiation from medical, occupational or environmental sources.

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

The expiration date for OMB approval of the information collection will be displayed on data collection instruments and materials. No special exception to this requirement is requested.

18. Exemptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.