





Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase 2 Pilot Planning

ISBN
978-0-309-31335-3

34 pages
web only
2014

Committee on the Analysis of Cancer Risks in Populations Near Nuclear Facilities-Phase 2 Pilot Planning; Nuclear and Radiation Studies Board; Division on Earth and Life Studies; National Research Council

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ANALYSIS OF CANCER RISKS IN POPULATIONS NEAR NUCLEAR FACILITIES

Phase 2 Pilot Planning

Committee on the Analysis of Cancer Risks in Populations
near Nuclear Facilities—Phase 2
Pilot Planning

Nuclear and Radiation Studies Board

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

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500 Fifth Street, NW

Washington, DC 20001

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This study was supported by Contract/Grant No. NRC-HQ-13-G-04-0051 between the National Academy of Sciences and the U.S. Nuclear Regulatory Commission. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the organizations or agencies that provided support for the project.

Cover image: Regional map of northeastern states and populations living in census tracts within 30 miles of nuclear power plants. Maps were created by Phase 1 committee member Lance Waller (Emory University, Atlanta, Georgia).

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NEAR NUCLEAR FACILITIES—PHASE 2 PILOT PLANNING**

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STEVEN M. BECKER, Old Dominion University, Norfolk, Virginia
ANDRE BOUVILLE, National Cancer Institute (retired), Bethesda, Maryland
JEAN D. BRENDER, Texas A&M Health Science Center, College Station
CHRISTIE R. EHEMAN, Centers for Disease Control and Prevention, Atlanta, Georgia
R. WILLIAM FIELD, University of Iowa, Iowa City
DANIEL O. STRAM, University of Southern California, Los Angeles
MARGOT TIRMARCHE, Nuclear Safety Authority of France, Cedex
JONATHAN C. WAKEFIELD, University of Washington, Seattle

Staff

OURANIA KOSTI, Study Director
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DANIEL O. STRAM, University of Southern California, Los Angeles
RICHARD J. VETTER, Mayo Clinic (retired), Rochester, Minnesota
SERGEY V. YUDINTSEV, Russian Academy of Sciences, Moscow, Russia

Staff

KEVIN D. CROWLEY, Director
JENNIFER A. HEIMBERG, Senior Program Officer
OURANIA KOSTI, Senior Program Officer
TONI GREENLEAF, Administrative and Financial Associate
LAURA D. LLANOS, Administrative and Financial Associate
DARLENE GROS, Senior Program Assistant
ERIN WINGO, Senior Program Assistant

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Analysis of Cancer Risks in Populations near Nuclear Facilities: Phase 2 Pilot Planning

THE STUDY CHARGE

The National Academy of Sciences (NAS) Committee on *Analysis of Cancer Risks in Populations near Nuclear Facilities: Phase 2 Pilot Planning* was charged with providing advice to NAS in performing a number of tasks related to the planning for a pilot epidemiological study of cancer risks in populations living near U.S. Nuclear Regulatory Commission (USNRC)-regulated nuclear facilities. Specifically, the Phase 2 Pilot Planning committee's task was to advise NAS on the following activities:¹

- Identify the processes for selecting qualified individuals and/or organizations to perform the epidemiological and dosimetric tasks required to carry out the pilot study.
- Initiate effluent release and meteorological data collection in preparation for estimating doses to the people who live near the pilot nuclear facilities.
- Identify state requirements for data sharing and transfer of health information.
- Obtain institutional review board (IRB) approvals for the study, as appropriate.
- Identify key stakeholders and processes for communicating with them.

Progress in carrying out these activities is described by NAS staff in Appendix B.² The committee was also tasked with preparing a brief report that provides advice to NAS on the methods and process for carrying out the pilot study. In fact, this committee was not initially tasked with preparing a report. It decided to do so because it determined during the course of the pilot planning that it needed a written record of its advice because of the strong interest by members of the public and the sponsor in its findings. The purpose of this brief report is to serve as a public record of the committee's advice to NAS on general methodological considerations involved in carrying out the pilot study. The NAS will consider the committee's advice when preparing the proposal to the sponsor and other documents related to carrying out the pilot study.

This pilot study was requested by the USNRC. The purpose of the pilot study, which was a recommendation of a previous NAS report (the Phase 1 report),³ is to evaluate the technical feasibility of implementing two study

¹ For the full statement of task for the phase 2 pilot planning study, see Appendix A.

² The committee is not responsible for the content of Appendix B.

³ The Phase 1 report can be accessed at http://www.nap.edu/catalog.php?record_id=13388.

designs recommended in that same report for carrying out an analysis of risks near nuclear facilities in the United States. If found to be feasible based on explicit criteria, the methods developed and tested in the pilot study could be used to conduct a nationwide study that would examine risks near all USNRC-regulated nuclear facilities. That is, the pilot study is part of a larger effort carried out by NAS at the request of the USNRC to characterize cancer risks in populations near nuclear facilities in the United States. This effort is carried out in two phases as illustrated in Figure 1.

The pilot study will be carried out under contract to the NAS by qualified individuals and/or organizations. The NAS and an NAS advisory committee will provide the overall study oversight. At the conclusion of the pilot study (i.e., at the end of the pilot execution step described in Figure 1), the NAS will prepare a consensus report with findings regarding the technical feasibility of carrying out an assessment of cancer risks at additional USNRC-regulated nuclear facilities.

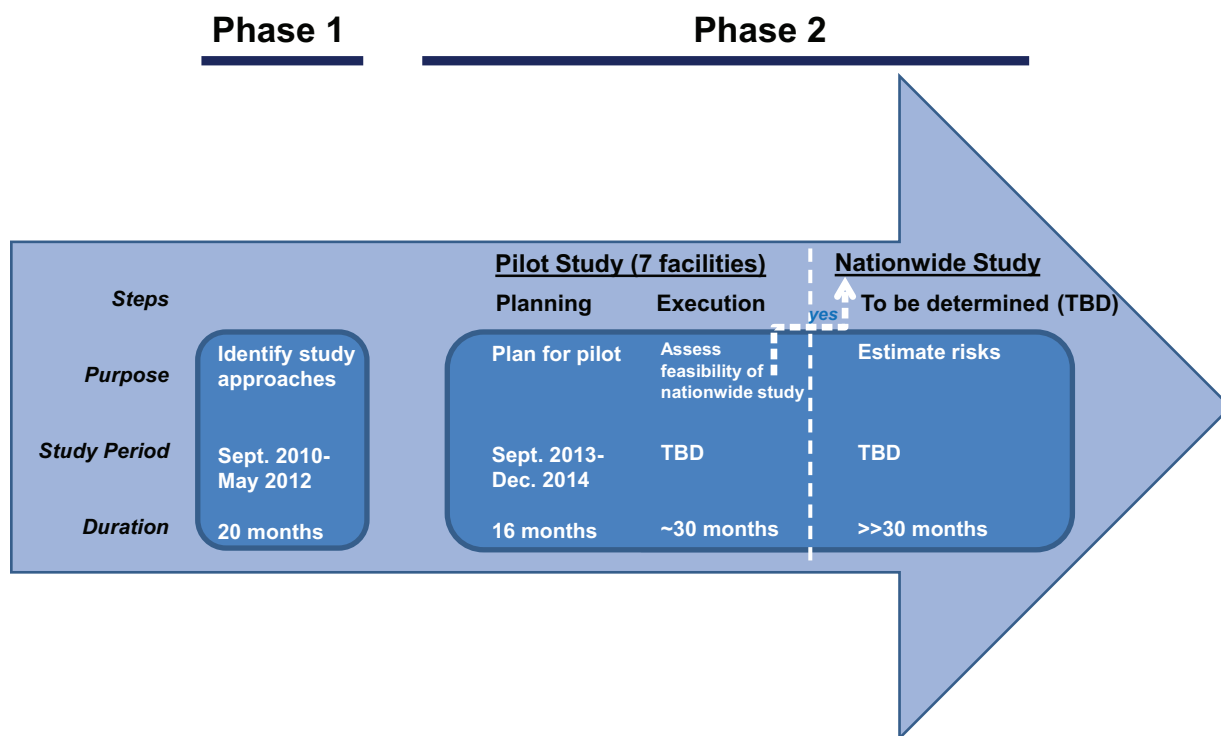


FIGURE 1 Phasing of the study on analysis of cancer risks in populations near nuclear facilities.

The USNRC asked NAS to undertake an assessment of cancer risks in populations near the nuclear facilities it regulates. NAS is performing this assessment in two phases. The Phase 1 study identified appropriate study designs to carry out an analysis of cancer risks near nuclear facilities in the United States. The Phase 1 report recommended two study designs appropriate for assessing cancer risks near nuclear facilities. It also recommended a pilot study of seven nuclear facilities to assess the technical feasibility of the recommended study designs. The Phase 2 study is the assessment of cancer risks. The pilot, which is part of the Phase 2 study, is being carried out in two steps: pilot planning and pilot execution. The pilot planning (current step) aims to plan for the pilot study. The pilot execution (next step) aims to carry out the pilot study and evaluate the technical feasibility of implementing the two study designs recommended in the Phase 1 study. If implementation of the study designs is feasible, the methods developed and tested in the pilot study could be used to conduct a nationwide study.

It is possible that even if feasible, the nationwide study will have low statistical power to detect any excess cancer risks in populations near nuclear facilities, if they exist. In that case the recommendation to proceed with the nationwide study will require weighing the potential for false positive associations together with the value of communicating with the public that the best information available, even if limited, is being used to answer its questions about cancer risks near nuclear facilities.

THE PILOT STUDY

The Phase 1 report recommended that seven nuclear facilities be selected for the pilot study of cancer risks in populations near nuclear facilities. These are:

- Dresden Nuclear Power Station, Morris, Illinois
- Millstone Power Station, Waterford, Connecticut
- Oyster Creek Nuclear Generating Station, Forked River, New Jersey
- Haddam Neck Plant, Haddam Neck, Connecticut
- Big Rock Point Nuclear Plant, Charlevoix, Michigan
- San Onofre Nuclear Generating Station, San Clemente, California; and
- Nuclear Fuel Services, Erwin, Tennessee.

The selected nuclear facilities include nuclear power plants that feature different reactor designs, years of operation, and current operational statuses. They also include a nuclear fuel cycle facility regulated by the USNRC, the Nuclear Fuel Services, which is a uranium fuel fabrication facility. A pilot study of these nuclear facilities will likely reveal the logistical difficulties and potential problems with accessing the required information to perform a nationwide study of cancer risks near USNRC-regulated nuclear facilities.

The study designs to be examined for their feasibility during the pilot study are a *population-level* (or *ecologic*) study and a *linkage-based case-control* study.

The *population-level*, or *ecologic*, study would describe cancer incidence and mortality in populations living in census tracts within approximately 50 kilometers (30 miles) of the nuclear facilities. This study would examine all radiogenic and relatively common cancer types at all ages in populations that are potentially exposed to radiation from nuclear facility operations during their operational histories to the extent feasible with available data. Organ doses to the population residing within a census tract will be assigned on the basis of radiation exposure calculated at the geographic centroid of the census tract.

The ecologic study is intended to answer the following questions:

1. Do cancer incidence and mortality vary by proximity to nuclear facilities?
2. Does cancer incidence or mortality reflect patterns of radiation exposure associated with the nuclear facility?

A *linkage-based case-control* study (hereafter referred to as the *case-control* study) would assess whether children younger than 15 years of age whose mothers lived close to the nuclear facilities at the time of their birth are at higher risk of developing cancer compared with those whose mothers lived farther away but within a 50-kilometer (30-mile) radius from the facilities. This study would attempt to provide a more focused assessment of the association of pediatric cancers in relation to *in utero* and early-life exposure to radiation to the extent feasible with available data. Organ doses to the fetus and child will be assigned on the basis of address where the mothers lived at the time of delivery of the children, as reported in birth certificates.

The case-control study is intended to answer the following questions:

1. Is a mother's residential proximity to a nuclear facility at time of delivery associated with cancer in her children?

2. Is estimated radiation exposure during pregnancy, early infancy, or childhood associated with childhood cancer occurrence?

The Phase 1 report recommended these ecologic and case-control study designs based on scientific merit, a preliminary analysis of their technical feasibility, and their ability to address public concerns about cancer risks near nuclear facilities.

To conduct the pilot study, NAS and its contractors will make use of existing health information from state cancer registries and vital statistics offices and data from the facilities, the state, and other entities on radioactive effluent releases. There is no intention to conduct interviews with people who live near the pilot nuclear facilities or to make new measurements of radioactive effluent releases from the facilities or in the environment. Still, the committee judges that the pilot study will likely require substantial effort and resources. The monetary cost for the retrieval of the data, construction of databases, and subsequent analyses will also be substantial.

THE COMMITTEE'S ADVICE TO NAS

This report comprises the committee's advice to NAS about general methodological considerations in carrying out the pilot study of cancer risks near nuclear facilities. It is not intended to be a comprehensive workplan of how to conduct the pilot study—this is outside the committee's study charge. The committee has also provided advice on study requirements and specifications that are described in a request for information that was issued to the public on October 7, 2014.⁴ These study requirements and specifications will be further developed at the next step of the pilot, the pilot execution step.

This brief report differs from typical reports of the National Research Council of the National Academy of Sciences and National Academy of Engineering that provide full supporting rationale and context for study findings and recommendations. The committee's advice to NAS was informed by the independent expert views of its members (see Appendix C for committee membership and expertise) and by information gathered during this study (see Appendix B). The committee held meetings to obtain information from the Electric Power Research Institute, the USNRC, subject-matter experts, several nonprofit organizations, and a variety of other stakeholder groups and individuals. It also received a number of written comments. Additional information was received when a subgroup of the committee hosted a public meeting near the Oyster Creek Nuclear Generating Station.

The committee's advice is presented in the form of 14 *considerations* related to the pilot study procedures (1-5), general methodologies (6-10) and specific methodologies for conducting the ecologic (11-13) and case-control studies (14). This brief report was subject to the National Research Council's report review process prior to its release. The names and affiliations of the reviewers are presented in Appendix D.

Procedural Considerations for Conducting the Pilot Study

1. The pilot study should be guided by the principles of independence, objectivity, ethics, openness, and excellence. In addition, transparency should be a central aim throughout the pilot study. This involves providing to interested parties information on the study process and regular updates on the study progress and making information accessible to the public (except where health data privacy rules or other ethical/legal considerations preclude disclosure).
2. Stakeholders should be given the opportunity to provide input on issues relevant to the study throughout the course of the pilot study. Such input could be obtained by following different and complementary models including forming a stakeholder advisory board and inviting stakeholders to speak at meetings. Ongoing communication with stakeholders during the study is essential.
3. All tasks of the pilot study should have a procedure manual that describes the specific approach to carrying

⁴ NAS issued a request for information (RFI) regarding the provision of research support and the associated costs for executing the pilot study. Attachment A to the RFI is the first draft of the pilot study requirements and specifications. See <http://nas-sites.org/cancerriskstudy/>.

out the task in sufficient detail to support replication by others. It is important to demonstrate transparency by making these procedure manuals available upon request.

4. The recommended study designs have several inherent limitations as well as limitations due to the unavailability of information to accurately reconstruct doses to the study populations. For example, in the absence of information on residential history, the recommended study designs by necessity will make assumptions about relevant exposures based on information about location of residence at one time point in the lifetime of the study populations, such as place of residence at time of diagnosis or death or place of residence of the mother at the time of delivery of the child. The pilot study should provide a comprehensive discussion of the assumptions and resulting uncertainties and their potential impacts on the risk assessments.
5. As noted in the Phase 1 report, the pilot study is intended to be a feasibility⁵ study, not a small-scale study of analysis of risks around the pilot nuclear facilities, and is also intended to identify potential modifications needed in the design of the nationwide study. These objectives of the pilot study should be made clear to the stakeholders.

Committee members have different views about whether the pilot study should test specific hypotheses and about the appropriateness and utility of presenting risk estimates from the pilot study. However, there was full agreement among committee members about the following three points:

- i. Any data collected during the pilot study will have limited use for estimating cancer risks in populations near each of the nuclear facilities or for the seven nuclear facilities combined because of the imprecision inherent in estimates from small samples.
- ii. Interpretation and communication of risk estimates from the pilot study, if reported, should be done with great caution.
- iii. The decision to proceed with the nationwide study should be based solely on conclusions related to feasibility and not on risk estimates.

General Methodological Considerations for Health and Dosimetry Data Processing

6. State cancer registries and vital statistics offices that hold the health information needed to conduct the pilot study should, to the extent possible, use the same protocol for preparing the data for release to the contractors who will carry out the pilot study. This includes protocols for linking cancer registration and birth records, assigning census tracts, and other procedures related to data acquisition. Having a common protocol makes it easier to compare and integrate data from different sources. The successful development and use of a common protocol would require regular communication among the state entities that hold the information, the contractors who will carry out the pilot study, and the NAS committee and staff that will provide study oversight.
7. The methodology used for the assessment of the annual doses from atmospheric and aquatic effluent releases from the individual nuclear power plants will be similar across the plants because the radionuclides released and the pathways of human exposure (inhalation, ingestion, and direct radiation) are the same. The specific model parameters used for the assessment of radionuclide concentrations in air and water, however, may differ from plant to plant depending on the complexity of the geography, weather patterns, nearby water bodies, and other factors. Independent of the models used, particular attention should be paid to the releases of carbon-14, which is believed to account for a substantial fraction of the doses in recent years.
8. A modified methodology for the assessment of the annual doses from atmospheric and aquatic effluent

⁵ Feasibility refers to the ability to

- Obtain sufficient nuclear facility airborne and waterborne effluent release and meteorology data,
 - Obtain cancer incidence and mortality data at the census-tract level, and
 - Link birth registration and cancer incidence data to identify eligible cases of pediatric cancers and matched controls.
- Explicit criteria for feasibility will be defined during the pilot execution step.

releases to that used for the nuclear power plants will need to be used for the Nuclear Fuel Services (NFS) facility. NFS is a uranium fuel fabrication facility that releases primarily alpha emitters, unlike nuclear power plants which release primarily beta and gamma emitters. Thus, for NFS, internal irradiation via inhalation or ingestion is the most important pathway of exposure.

9. The pilot study should independently validate a sample of effluent release data reported by each of the pilot nuclear facilities. Validation of the releases and dose estimates can include demonstrating that the doses could not have exceeded specific levels based on detection limits of environmental monitoring by independent entities such as states and research organizations.
10. There should be an investigation of available data on variations in natural background radiation levels with distance and direction from the pilot nuclear facilities. Such an investigation would determine whether sufficient information exists for consideration of natural background radiation as a potential confounder in the epidemiological analysis.

Specific Considerations for the Pilot Ecologic Study of Cancer Incidence and Mortality at the Census Tract Level

11. Risk estimates from the ecologic study should be interpreted with caution because of the inherent limitations of the study design; these include aggregation of information and the difficulty of characterizing within-area (census tract) variability in exposures and potential confounders. The pilot ecologic study could provide indications of the heterogeneity of populations across census tracts and possible confounding by characterizing demographic differences of the populations in relation to proximity to the nuclear facilities.
12. Investigation of available data conducted by NAS staff during the current study highlighted two limitations of information collected by the state vital statistics offices that may compromise the feasibility of an ecologic study of cancer mortality:
 - i. The year at which address at time of death from cancer⁶ is first recorded electronically ranges from 1949 to 2008. In fact, five out of the seven pilot states for which information is available started collecting address at time of death from cancer electronically in 2000 or later.
 - ii. Information on the specific cancer site as underlying cause of death may be missing from the death certificate in some states. Also, in some cases, if a cancer metastasizes, the metastatic site may be listed as the underlying cause of death instead of the primary cancer site.
13. The abovementioned limitations in carrying out and interpreting findings from the ecologic study and the uncertainties in estimating exposure for a population where data for individuals are not known outweigh the benefits from performing a detailed dose assessment. Still, the ecologic study should include a facility-specific dose assessment in addition to a distance-based analysis of risks.⁷ This dose assessment can be based on simplifying assumptions (e.g., that there have been no changes with time on water use, land use and food consumption and origin) and using annual average concentrations of radionuclides released and commensurate averaging of meteorological data. These simplifications would reduce the amount of effort and resources required; however, they would still be substantial because doses need to be calculated starting from the first year that the nuclear facility of interest started operation in order for the study to

⁶ Information on address at time of death from cancer is central to estimating cancer mortality risks for the census tracts within 50 kilometers from the pilot nuclear facilities.

⁷ This is because distance alone is not a good indicator of the doses received by the populations of the various census tracts. There are several reasons why the dose pattern around a nuclear facility may be complex and cannot be predicted using distance alone. Two are discussed here:

- i. The distribution of wind speed and direction is not isotropic around a nuclear facility and therefore airborne releases are not transported uniformly in all directions.
- ii. The population of a given census tract would typically consume water and foodstuffs that, at least in part, originate from another census tract.

assess cancer risks later in life. For some nuclear facilities this would require estimating releases and calculating doses associated with about 55 years of facility operation.

Specific Considerations for the Pilot Case-Control Study of Childhood Cancers

14. The dose assessment will start as early as 16 years before a case is diagnosed.⁸ Many assumptions will have to be made to estimate risks because residential history and dietary and lifestyle habits of the children examined will not be available. The dose assessment should use more detailed information than that for the ecologic study to determine concentrations of radionuclides released and time-specific parameters such as water use, land use, and amounts and origins of consumed foodstuffs.

⁸ This applies to a case diagnosed at age 15. Since the case-control study will attempt to answer the question of whether estimated radiation exposure during pregnancy is associated with childhood cancer occurrence, doses will be calculated also for the 9 months (for convenience rounded to 1 year) of pregnancy.

Appendix A

Statement of Task

The National Research Council will perform a pilot study of cancer risks in populations near seven U.S. Nuclear Regulatory Commission (USNRC)-licensed nuclear facilities using two epidemiologic study designs: (i) an ecologic study of multiple cancer types of populations of all ages and (ii) a record-linkage-based case-control study of cancers in children. The pilot study will focus on the five activities described below:

1. Obtain nuclear facility airborne and waterborne effluent release and meteorology data and digitize these data into a form that is usable for dose estimation.
2. Develop a computer model to obtain estimates of absorbed doses to individual organs resulting from effluent releases.
3. Obtain cancer incidence and mortality data at the census-tract level to assess the feasibility of the ecologic study.
4. Link birth registration and cancer incidence data to identify eligible cases of pediatric cancers and matched controls to assess the feasibility of the record-linkage-based case-control study.
5. Develop processes for involving and communicating with the public.

The pilot study will have two steps: Pilot Planning and Pilot Execution. The activities associated with Pilot Planning are:

- Appoint the study committee.
- Identify the processes for selecting qualified individuals and/or organizations to perform the epidemiology and dosimetry tasks.
- Initiate effluent release and meteorological data collection.
- Investigate availability of existing models or need to create a new model for dose estimation.
- Identify state requirements for data sharing and transfer of health information.
- Obtain IRB approvals for the study, as appropriate.
- Identify key stakeholders and processes for communicating with them.
- Prepare a brief committee-authored report that provides the committee's advice to the National Research Council on the study design of and process for executing the pilot.

At the conclusion of the Pilot Execution step, the National Research Council will prepare a consensus report with findings regarding the scientific feasibility of carrying out an assessment of cancer risks at additional USNRC-licensed facilities. The report will also include, if feasible, an analysis of cancer risks in the populations near the seven pilot facilities.

Appendix B

NAS Staff Progress with Responding to the Statement of Task

The activities described below were carried out by NAS and were overseen by the expert committee.¹

APPOINT THE STUDY COMMITTEE

Members of the committee were chosen on the basis of their knowledge and expertise in the scientific disciplines needed to carry out the study. The NAS provisionally appointed the expert committee for the study on October 23, 2013. An additional expert, Dr. Christie Ehemann, was provisionally appointed to the committee on January 27, 2014, to provide expertise in data availability and release criteria from cancer registries. The slate of provisional committee appointments was open to public comment for 20 calendar days and all appointments were finalized February 17, 2014.

IDENTIFY THE PROCESSES FOR SELECTING QUALIFIED INDIVIDUALS AND/OR ORGANIZATIONS TO PERFORM THE EPIDEMIOLOGY AND DOSIMETRY TASKS

The collection and analysis of dosimetry and epidemiology data will be carried out by individuals and/or organizations whose work will be overseen by NAS and a NAS advisory committee. Qualified individuals and/or organizations to perform data collection and analysis will likely be identified by issuing a request for proposal (RFP). An RFP is a type of bidding solicitation in which NAS will announce that funding is available for investigators to provide research support for the pilot study and will outline the bidding process and contract terms. The RFP will be open to a wide range of bidders and will create open competition among qualified individuals and/or organizations. The decision on who will be awarded the contract will be made by NAS.

INITIATE EFFLUENT RELEASE AND METEOROLOGICAL DATA COLLECTION

NAS staff considered multiple sources of information to obtain effluent release and meteorological data. Data collection efforts primarily focused on obtaining effluent release reports for the seven pilot facilities because it was

¹ With the exception of the first activity, *Appoint the Study Committee*, which was carried out by NAS staff using the NAS process for committee appointments. See <http://www.nationalacademies.org/studyprocess/>.

expected that they would contain the data required to estimate doses to the study populations. In the case of the Dresden Nuclear Power Plant, a large portion of the population living within 50 kilometers (30 miles) from the plant is also exposed to releases from two neighboring plants: Braidwood and LaSalle. These neighboring plants will also be considered in estimating doses to that portion of the population; therefore, effluent release reports from these nuclear power plants need to be collected as well.

EFFLUENT RELEASE DATA

Required first by the Atomic Energy Commission and now by the U.S. Nuclear Regulatory Commission (USNRC) (according to 10 CFR § 50.36(a)(2)), licensees submit effluent release reports during operation of the facility and during decommissioning. The licensee's technical specifications (required by 10 CFR § 50.36(a)(2)) also contain reporting requirements for radioactive effluents. The licensee's final safety analysis report identifies commitments regarding the content of nuclear power facilities' effluent release reports, which include the quantity of principal radionuclides released to unrestricted areas in gaseous and liquid form including additional information needed to estimate maximum potential doses to the public. This information includes the locations of the release points, information on batch and/or episodic releases, and meteorological data such as wind speed, direction, and stability. The effluent release reports from recent years routinely list releases for 20 to 35 radionuclides. Carbon-14, a radionuclide of particular interest today, was first consistently reported in licensees' effluent release reports beginning in 2010. For licensees of facilities processing special nuclear material (e.g., Nuclear Fuel Services), the USNRC technical specifications (10 CFR § 70.59) define similar effluent release reporting requirements.

The effluent release reports were collected from the following three sources:

1. The USNRC's official record-keeping system known as the Agencywide Documents Access and Management System (ADAMS).²
2. The USNRC's offsite archival storage facility.
3. The nuclear facilities.

At the time this report was written,³ 68 percent of effluent release reports produced by the pilot facilities (including Braidwood and LaSalle) from the start of operations to 2013 were retrieved and determined to be human-readable. As shown in Table B.1, a large percentage of the reports from 1995 to 2013 (92 percent) and the majority of reports from 1975 to 1994 (74 percent) have been retrieved and determined to be human-readable. However, very few reports prior to 1975 have been collected (fewer than 25 percent). The USNRC is searching its offsite storage facility and working with its licensees to retrieve these early effluent release reports.

The effluent report retrieval efforts that took place during the pilot planning study have resulted in the public access to over 100 additional effluent release and other related reports.⁴ Approximately 70 of these are Nuclear Fuel Services reports previously restricted from public access. The remaining reports were provided by three licensees in response to a request from NAS staff (Oyster Creek) or USNRC staff (San Onofre and Dresden) for effluent release reports from early (pre-1975) years of operation.

Efforts to collect additional effluent release reports or identify better-quality copies of the reports are ongoing. However, it is possible that some gaps will remain. Effluent release data for the years when reports are missing will need to be interpolated from available reports, or data from annual summary reports⁵ may be used. In 1977, the

² Information on ADAMS and its various libraries can be found at <http://www.nrc.gov/reading-rm/adams.html>. The web-based ADAMS Publicly Available Records System (PARS) Library was used to identify and retrieve the most recent effluent release reports (reports dating from approximately 1995 and later). Reports retrieved directly from ADAMS PARS Library are considered official reports. The web-based ADAMS Public Legacy Library was used to identify earlier effluent release reports; these are stored on microfiche. Reports retrieved from microfiche are not considered official effluent release reports.

³ That is, as of 11/12/2014.

⁴ These reports can be downloaded from the ADAMS PARS Library.

⁵ Several sources of annual effluent release summary reports exist, including the USNRC's NUREG 2907 series. This series, which was originally produced by Brookhaven National Laboratory for the USNRC, contains yearly summaries of nuclear power facilities' effluent releases. NAS staff has collected summaries from 1980 through 2009.

TABLE B.1 Summary Description of Effluent Release Reports Retrieved

Nuclear Facility	Years of Operation ^a	Percentage of Available and Readable Reports		
		Pre-1974	1975-1994	1995-2013
Big Rock	1962-1997	0	69	84
Braidwood	1987-present	N/A	56	89
Dresden	1959-present	13	83	90
Haddam Neck	1968-1996	0	92	89
LaSalle	1982-present	N/A	86	95
Millstone	1970-present	0	51	100
Oyster Creek	1969-present	100	62	95
San Onofre	1967-2012	93	85	95
Nuclear Fuel Services	1957-present	3	73	92
Average Percentage		21	74	92

^aAccounts for the operation of the first unit at a given site.

Environmental Protection Agency (EPA) produced a report on annual summed measurements of effluent releases from nuclear power facilities. The report includes a listing of yearly summed releases of 27 isotopes. For some radionuclides, including carbon-14, it may be possible to fill gaps in effluent release data by scaling to power production.

METEOROLOGICAL DATA

Although nuclear facilities collected meteorological data⁶ as frequently as every hour, only quarterly or semiannual joint frequency distributions are reported in the effluent release reports, and the data are not always readable primarily because of the small font size. Also, data often are not available over the entire period of interest for this study.

Other sources of information for meteorology need further exploring. One such source is the National Center for Atmospheric Research Reanalysis Project. This project has used measured data from different sources (e.g., weather stations, ships, aircraft, satellites) to forecast, at a minimum daily average, meteorological information at different locations. Information from this source is available from 1948 onward.

INVESTIGATE AVAILABILITY OF EXISTING MODELS OR NEED TO CREATE A NEW MODEL FOR DOSE ESTIMATION

A number of models exist that can be adapted and used to obtain estimates of atmospheric and aquatic dispersion of effluent releases, internal and external radiation exposure, and age-dependent absorbed doses to individual organs. However, considering that carbon-14 emissions may have been a major contributor to dose in recent years, an improved model for estimating dose from carbon-14 may need to be developed.

Off-the-shelf modified Gaussian plume dispersion models such as those recommended by the EPA or the USNRC⁷ will be sufficient for use in estimating average air concentrations of radionuclides released. However,

⁶ The meteorological data included in the facility's effluent release reports are wind speed, direction, and stability. They do not include precipitation.

⁷ For example, REXOQ2, a PC version of the USNRC program XOQDOQ (Sagendorf J.F., Goll J.T., and Sandusky W.F., 1982, XOQDOQ: Computer Program for the Meteorological Evaluation of Routine Effluent Releases at Nuclear Power Stations, NUREG/CR-4380, U.S. Nuclear Regulatory Commission), GASPAR (Eckerman K.F., Congel F.J., Roedeldein A.K., and Pasciak, W.J., 1980, User's Guide to GASPAR Code, NUREG/CR-0597, U.S. Nuclear Regulatory Commission); Strenge D. L.T., Bander J., and Soldat, J.K., 1987, GASPAR II—Technical Reference and User Guide, NUREG/CR-4653, PNL 5907, Pacific Northwest National Laboratory, Richland, WA), AERMOD (Cimorelli A.J., Perry S.G., Venkatram A., Weil J.C., Paine R.J., Wilson R.B., Lee R.F., Peters W.D., Brode R.W., Paumier J.O., 2004, AERMOD: Description of Model Formulation, EPA-454/R-03-004, U.S. Environmental Protection Agency, http://www.epa.gov/scram001/7thconf/aermod/aermod_mfd.pdf).

some nuclear facilities may require more complicated models because of their geographies. Models such as the Hybrid Single Particle Lagrangian Integrated Trajectory (HYSPLIT) model⁸ or the Regional Atmospheric Transport Code for Hanford Emission Tracking (RATCHET)⁹ model could be used for estimating air concentrations at these facilities.

Reviews of models of aquatic transport in rivers, lakes, estuaries, oceans, and other water bodies are available.¹⁰ The suitability of a model to a given site will depend on the availability of model input data such as direction and speed of flow of currents, both natural and plant-induced; intensity of turbulent mixing; size, geometry, and bottom topography of the water body; and characteristics of suspended and bottom sediments.

IDENTIFY STATE REQUIREMENTS FOR DATA SHARING AND TRANSFER OF HEALTH INFORMATION

Health information needed to conduct the recommended ecologic and case-control studies is collected and maintained by the state cancer registries and vital statistics offices. These two entities are typically found in the state's department of public health and are separate in terms of administrative processes, statutes, and regulations. Cancer registries collect information related to incident cancer cases. Vital statistics offices collect information related to deaths (including cancer deaths) and births.

The seven pilot sites are located in six states as shown in Table B.2. These six states will need to approve release of health information that is relevant to the study. Additional states whose populations reside within 50 kilometers (30 miles) of the pilot nuclear facilities will also need to approve release of information on their portion of the population that lives near these facilities.

NAS staff visited several pilot states¹¹ and engaged in discussions with representatives of the state's cancer registries and vital statistics offices to better understand data availability and release criteria. The information collected by NAS staff from its visits with the state offices is summarized below in terms of data availability and completeness, linkages, and policies and mechanisms.

DATA AVAILABILITY AND COMPLETENESS

The terms *data availability* and *data completeness* are used here as an estimate of totality of features of the datasets to be requested from the cancer registries and vital statistics offices to conduct the pilot study. Because doses to the populations and/or individuals will be based on their place of diagnosis (ecologic study of cancer incidence), death (ecologic study of cancer mortality), or birth (case-control study), availability of address at time of diagnosis, death, or birth is essential for conducting the pilot.

Address at Time of Diagnosis

Table B.3 summarizes the availability and completeness of information on address at time of cancer diagnosis from the pilot states. Note that the state representatives were not asked to query their databases to provide precise information on address availability; instead they were asked to provide rough estimates of address information completeness. In addition, the percentages given by the states on address information completeness (noted as per-

⁸ Draxler R.R., Hess, G.D. 1998: An overview of the HYSPLIT_4 modeling system of trajectories, dispersion, and deposition. *Aust Meteor Mag*, 47, 295-308.

⁹ Ramsdell J.V., Jr., Simonen C.A., and Burk K.W., 1994. Regional Atmospheric Transport Code for Hanford Emission Tracking (RATCHET). PNWD-2224 HEDR, Battelle, Pacific Northwest National Laboratories, Richland, WA.

¹⁰ USNRC Guide 1.113, Estimating Aquatic Dispersion of Effluents from Accidental and Routine Reactor Releases for the Purpose of Implementing Appendix I from Light-Water-Cooled Reactors, Revision 1. April 1977; Till J.E., Grogan H.A. (eds), 2008. *Radiological Risk Assessment and Environmental Analysis*, Oxford University Press.

¹¹ Information related to the North Carolina cancer registry and vital statistics office and the New Jersey vital statistics office was collected by a phone interview. At the time of this writing (November 2014), NAS staff has not collected the relevant information from Rhode Island or New York.

TABLE B.2 States That Will Contribute Data to the Pilot Study

	Pilot Nuclear Facility
Main States	
California	San Onofre
Connecticut	Millstone, Haddam Neck
Illinois	Dresden
Michigan	Big Rock Point
New Jersey	Oyster Creek
Tennessee	Nuclear Fuel Services
Additional States	
Rhode Island	Millstone
New York	Millstone
North Carolina	Nuclear Fuel Services

TABLE B.3 Availability of Address at Cancer Diagnosis Information from Pilot States

State	Year of Initial Operation	1st Year That Address Exists in Almost All Records	% Records Missing Address	Geocoded?
CA	1988 ^a	1988	6	yes
CT	1935 ^b	1992	~0.3	yes
IL	1986 ^c	1986	~10	yes
MI	1981 ^a	late 1990s	10	yes
NC	1980 ^c	1995	15	yes
NJ	1979 ^a	1995	~5	yes, mostly
TN	1986 ^c	2004	~5	yes

^aPart of the state or a selected population within the state is part of the Surveillance, Epidemiology, and End Results (SEER) program.

^bEntire state is part of the SEER program.

^cEntire state is part of the National Program of Cancer Registries.

cent records missing address on Table B.3) may not represent completeness of the information in the study areas (i.e., 50 kilometers around the pilot nuclear facilities). In fact, a number of state representatives commented that in rural areas such as those near nuclear facilities, address information completeness may be lower than state averages.

As shown in Table B.3, the time periods for which address at time of cancer diagnosis is available electronically is about 1995, although there is some variability across states. Addresses are missing or are incomplete for some records (i.e., described as P.O. Box or rural route number). All states geocode¹² address information to census tract at least for the more recent years. Some state cancer registries geocode address information in-house whereas others contract with geocoding specialists. Cancer registries may have used different geocoding tools to geocode their data, leading to different match rates¹³ and level of positional accuracy of the geocoded data.

Veterans Affairs Cases

The U.S. Department of Veterans Affairs (VA) changed its policy regarding the sharing of VA cancer data in 2007. This policy change results in incomplete reporting of VA hospital patients to some state cancer registries

¹² Geocoding is the process of assigning geographic coordinates to an address so that it can be placed as a point on a map.

¹³ Defined as the ratio between the total number of automatically geocoded addresses and total number of addresses to be geocoded. See Zhan F. B., Brender J. D., De Lima I., Suarez L., Langlois P. H., 2006, Match rate and positional accuracy of two geocoding methods for epidemiologic research, *Ann Epidemiol*, 16(11):842-849.

and the inability of the states to share data with third parties requesting cancer incidence data from state cancer registries.

NAS staff requested information on the proportion of VA hospital cancer cases within the pilot states to roughly estimate the impact of the missing VA hospital patients in the pilot study. The annual percentage of estimated VA hospital cases ranged between 0.5 and 2 percent of the total number of cases reported annually within the state.

Address at Time of Death

Of the seven state vital statistics offices (California, Connecticut, Illinois, Michigan, North Carolina, New Jersey, and Tennessee) that provided information on availability of address at time of death, all currently have that information in electronic form. However, the first year for which the information is available electronically varies greatly: 2005, 1949, 2008, 2000, 2000, 2006, and 1990, respectively. Although the information is not available electronically prior to the years shown above, it is available in paper copies of the death certificate. Transfer of the information from the death certificate to an electronic database is estimated to cost about \$1.00 per death certificate.¹⁴ Given that there are about 15,000-55,000 cancer deaths annually in each of the pilot states, transfer of the information is an expensive and time-consuming task. Most states reported that address at time of death is not geocoded.

Address at Time of Birth

Address at time of birth is needed for the case-control study and selection of appropriate cases and controls. This address is actually the address of residence of the mother at the time of delivery of the child and for the purposes of the study is also assumed to be the mother's residence during pregnancy and the child's residence until he/she is 15 years old. Typically, this address is available electronically in vital statistics office databases from 1995 onward with some exceptions. For example, in Illinois the information only exists electronically since 2010. Most states reported that address at time of birth is not geocoded.

Other Data

NAS staff inquired about availability of additional information that is relevant to the ecologic and case-control study designs. A sample of the variables of interest is listed in Table B.4. States reported that they collect this information.

There may be variability across and within states in missing or incorrect information on the death certificates. Examples include lack of information on cancer site or, if a cancer metastasizes, listing of the underlying cause of death as the metastatic site instead of the primary cancer site.

POLICIES AND MECHANISMS

The health information required for the pilot study generally is not publicly releasable because of privacy and patient protection federal and/or state regulations. Cancer registries and vital statistics offices will need to review the research proposal and protocol for the NAS pilot study before approving the release of information. Some states have multiple levels of protocol approvals; in general it would take 3-6 months for a protocol to be approved by the state IRB.

All of the data discussed previously (e.g., address at time of diagnosis or death, address at time of birth, and those listed in Table B.4) could be released to the investigators upon approval of the research protocol by the state's IRB. States reported that there are no different restrictions for release of the information for children and adults. An exception was health information and other identifiable information related to the mother and reported

¹⁴ Communication with state of Michigan cancer registry and vital statistics office director. This estimate was supported by representatives of other state vital statistics offices.

TABLE B.4 Sample Variables of Interest Collected from the States

	Ecologic Study	Case-Control Study
Cancer Registries		
Year of diagnosis	X	X
Age at diagnosis	X	X
Gender	X	X
Race/ethnicity	X	X
Cancer site and histology	X	X
Vital Statistics Offices		
Death Records		
Year of death	X	N/A
Age at death	X	N/A
Gender	X	N/A
Race/ethnicity	X	N/A
Underlying cause of death		N/A
Contributing cause of death		N/A
Cancer site for	X	
• underlying cause of death		
• contributing cause of death		
Birth Records		
Mother's age	N/A	X
Mother's race/ethnicity	N/A	X
Child's birth weight	N/A	X

N/A (not applicable) means that the specific variable is not needed to carry out one of the two recommended study designs.

in the Illinois birth certificates.¹⁵ NAS staff did not discuss with the Illinois vital statistics office representatives whether this barrier could be overcome.

DATA LINKAGES

To conduct the case-control study, birth records will be linked with cancer registration records to identify suitable cases and controls. None of the pilot states reported to *routinely* perform the type of linkages required for this study. However, all states had some experience with data linkages. Since no unique identifier such as the child's or the mother's social security number is typically present in both administrative databases, the linkage would be (at least partially) probabilistic using variables such as name, date of birth, gender, race of the child, and possibly address at time of birth.

The pilot states generally indicated that the linkages would happen *in-house*. However, some states indicated that they could release the data to the investigators to perform the linkages in their facilities, and other states were open to the idea of the investigators performing the linkages in the state's facility. Although the specifics were not discussed, cost and time frame for release of the linked information would vary based on the approach.

OBTAIN IRB APPROVALS FOR THE STUDY, AS APPROPRIATE

Studies that involve health information of individuals require IRB approvals to ensure ethical conduct and protection of information. The IRB has the authority to approve, require modifications to secure approval, or disapprove the activities of the pilot study. During the pilot planning step, no health data were requested from the

¹⁵ <http://www.ilga.gov/commission/jcar/admincode/077/077005000000200R.html>.

cancer registries and vital statistics offices; therefore, there was no need to obtain IRB approvals. However, IRB approvals will be required for the pilot execution step when health data will be requested from the state cancer registries and vital statistics offices. All entities involved in carrying out the pilot study, that is, the state cancer registries and vital statistics offices, NAS, and NAS contractors, will be required to obtain IRB approvals from the states and from their institutions. Some states may require additional approvals, for example, from affiliated regulatory groups. State representatives estimate that it will take about 3-6 months to obtain the needed approvals to carry out the pilot study. IRB (and other approvals) will need to be renewed annually and whenever modifications are made to the previously approved protocol.

IDENTIFY KEY STAKEHOLDERS AND PROCESSES FOR COMMUNICATING WITH THEM

The committee and staff used several processes to communicate with and invite the participation of interested members of the public during the pilot planning. These included:

1. The NAS current project website (<http://www8.nationalacademies.org/cp/>) which lists committee biographies and meeting dates and agendas.
2. A dedicated project website (<http://nas-sites.org/cancerriskstudy/>) supplementing the NAS website to provide additional information of interest to the public about the study and further enable interested parties to submit information for the committee's consideration.
3. A listserv to notify interested parties about project milestones such as appointment of the study committee and meeting dates, locations, and agendas.
4. Web conferencing for remote participation of interested members of the public unable to be present at the committee's information-gathering sessions.
5. Public-comment sessions scheduled at the end of the committee's information-gathering meetings in Washington, D.C., and Irvine, California.
6. A public meeting near the Oyster Creek Generating Station located in New Jersey.
7. Creation of a Frequently Asked Questions document¹⁶ that discusses several issues related to the pilot, the methods and nuclear facilities selected, processes of the NAS, and ways for interested members of the public to be kept informed about the study and provide comments.

OTHER ACTIVITIES

NAS staff performed additional activities not specified in the statement of task but deemed necessary for planning the pilot. Sources of information for these additional activities were:

- The February 18, 2014, conference call with Dr. Benjamin Zhan, professor and director, Texas Center for Geographic Information Science, and Dr. Francis Boscoe, research scientist, New York State Cancer Registry.
- Representatives of the state cancer registries and vital statistics offices.
- NAS staff research.

INVESTIGATING THE PROCESS FOR GEOCODING ADDRESS INFORMATION

The pilot study will likely require a substantial effort to geocode addresses because:

1. Most cancer registries only geocode data for the most recent years.
2. Vital statistics offices typically do not geocode data.
3. States and the different offices within a state are not required to use the same protocol for geocoding data.

¹⁶ See: <http://nas-sites.org/cancerriskstudy/>.

Representatives of a number of pilot state cancer registries suggested that it is important for a multistate study such as this pilot to use the same protocol for geocoding address at time of diagnosis across states. (The same applies for address at time of cancer death and address where the mother lived at the time of delivery of the child.) This is because different geocoding methods may result in different match rates and level of positional accuracy of the geocoded data. Also, it is easier to compare and integrate data created using the same protocol.¹⁷ A number of commercial and open-source geocoding tools are available today. Eight tools were evaluated for their performance and compared for cost and licensing.¹⁸

The quality of the original address data is an important factor in determining the performance of a geocoding tool. Typically, about 80-90 percent of addresses from health-related datasets can be automatically geocoded using current geocoding tools.¹⁹ It would take about 2 seconds on average to automatically geocode an address using a typical computer. Addresses that cannot be geocoded automatically require manual intervention/interactive geocoding. The manual intervention/interactive geocoding process can range from checking an address for obvious errors that can easily be corrected to investigating means to find more information on the address from the record, websites, or other administrative databases.²⁰ Representatives of the Illinois cancer registry said that it may take up to an hour to manually geocode a single address.

Dr. Benjamin Zhan, Texas Center for Geographic Information Science, who briefed the committee, said that the cost of a geocoding project correlates to the number of records that need to be processed manually.

INVESTIGATING AVAILABILITY OF CENSUS DATA

Linking a geocoded cancer record (or other) address with census areas is used to determine characteristics of the populations living in an area in which an address is located, such as demographic, socioeconomic, household, and health insurance data. This information is available at the census tract level in the 2000 and 2010 census data. Subscription sources such as SimplyMap have additional information on lifestyle factors of the populations residing in a census tract, such as percentage of nonsmoking population, percentage of people who eat healthily, percentage of people who exercise regularly, and percentage of nonalcoholic population for the same years. For earlier time periods (1960, 1970, 1980, and 1990), some of these variables are available at the census tract level through commercial vendors, for example, Geolytics.²¹ However, since the U.S. Census Bureau did not fully tract the United States until 1990, pre-1990 data are available only for urban areas.

In addition to the decennial data available from the sources mentioned above, the U.S. Census Bureau performs the American Community Survey (ACS), an ongoing statistical survey that samples a small percentage of the population every year. The estimates at the census tract level are based on rolling 5-year data periods starting from 2005. Example variables in the ACS data include age, gender, race, family and relationships, income and benefits, health insurance, education, veteran status, disabilities, location of work and how people get to their office, and how much people pay for some essentials.

¹⁷ Goldberg, D.W., 2008, A Geocoding Best Practices Guide. North American Association of Cancer Registries, https://www.naacr.org/LinkClick.aspx?fileticket=ZKekM8k_IQ0%3D&tabid=239&mid=699 (accessed November 2014).

¹⁸ Swift J.N., Goldberg D.W., Wilson J.P., 2008, Geocoding Best Practices: Review of Eight Commonly Used Geocoding Systems. University of Southern California GIS Research Laboratory Technical Report No 10, <http://spatial.usc.edu/wp-content/uploads/gislabtr10.pdf> (accessed November 2014).

¹⁹ Wang Y., O'Leary L.A., Rickard R.S., Mason, C.A., 2009, Geocoding capacity of birth defects surveillance programs: Results from the National Birth Defects Prevention Network Geocoding Survey. *J Registry Manage*, 37(1):22-26; Zhan F.B., Brender J.D., De Lima I., Suarez L., Langlois P.H., 2006, Match rate and positional accuracy of two geocoding methods for epidemiologic research, *Ann Epidemiol*, 16(11):842-849.

²⁰ Goldberg D.W., Wilson J.P., Knoblock C.A., Ritz B., Cockburn M.G., 2008, An effective and efficient approach for manually improving geocoded data. *Int J Health Geogr*, 7(1):60.

²¹ See <http://www.geolytics.com/USCensus,Census-1970-1980-1990,Categories.asp>.

Appendix C

Biographical Sketches of Committee and Staff

Jonathan M. Samet, M.D., a pulmonary physician and epidemiologist, is currently professor and Flora L. Thornton Chair for the Department of Preventive Medicine at the Keck School of Medicine at the University of Southern California and director of the University of Southern California Institute for Global Health. He received an A.B. degree in chemistry and physics from Harvard College, before receiving the M.D. from the University of Rochester School of Medicine and Dentistry. He also has an M.S. in epidemiology from the Harvard School of Public Health. Dr. Samet has investigated diverse health issues using epidemiological approaches. His research has focused on the health risks of inhaled pollutants—particles and ozone in outdoor air and indoor pollutants including secondhand smoke and radon. He has also investigated the occurrence and causes of cancer and respiratory diseases, emphasizing the risks of active and passive smoking. He has served on numerous committees concerned with using scientific evidence for the development of policy to protect public health. He was a member of the Biological Effects of Ionizing Radiation (BEIR) IV committee and chair of BEIR VI. For several decades, he has been involved in global health focused on tobacco control and air pollution. He currently chairs the Food and Drug Administration's Tobacco Products Scientific Advisory Committee. He was appointed to the National Cancer Advisory Board in 2011. Dr. Samet received the Surgeon General's Medallion in 1990 and 2006, the 2004 Prince Mahidol Award for Global Health awarded by the King of Thailand, and the 2006 Public Service Award of the American Thoracic Society. He was elected to the Institute of Medicine of the National Academies in 1997.

Harold L. Beck is an expert in radiation dose reconstruction. A physicist for the U.S. Department of Energy (DOE)/Atomic Energy Commission for over 36 years, he retired in 1999 as the director of the Environmental Science Division of the DOE Environmental Measurements Laboratory (EML) in New York City and is presently a private consultant conducting various dose reconstructions in cooperation with scientists at the National Cancer Institute (NCI) and Vanderbilt University. During his tenure at EML, he also served as director of the EML Instrumentation Division and as acting deputy director of the laboratory. Mr. Beck has authored well over 100 publications on radiation physics, radiation measurement, dose reconstruction, environmental radiation, and radiation dosimetry. His efforts in the development of the scientific approach to reconstructing fallout doses to the U.S. population from aboveground nuclear weapons testing in Nevada earned him the DOE Meritorious Service award in 1988, the second-highest award in the department. Mr. Beck served as scientific vice president for radiation measurements and dosimetry of the National Council on Radiation Protection and Measurements (NCRP) from 1996 to 2003, and in 2004 was elected to distinguished emeritus membership in NCRP. From 2004 to 2006, he served as

a member of the National Research Council's Board on Radiation Effects Research/Nuclear and Radiation Studies Board. He currently serves as a member of the Veterans (federal advisory) Board on Dose Reconstruction and the U.S. Scientific Review Group, Department of Energy Russian Health Studies Program. He has served as an expert member or chair on a number of NCRP and National Research Council scientific studies related to radiation dosimetry. He served as a member of the National Research Council's Committee on Analysis of Cancer Risks in Populations near Nuclear Facilities: Phase 1.

Steven M. Becker, Ph.D., is professor of community and environmental health in the College of Health Sciences at Old Dominion University in Norfolk, Virginia. He is an internationally recognized expert on the public health, risk communication, and preparedness and response issues associated with large-scale emergencies and disasters. Dr. Becker has nearly two decades of field experience at the sites of major incidents around the world, including the 1999 nuclear criticality accident in Tokaimura, Japan, and the 2001 foot-and-mouth disease outbreak in the United Kingdom. Most recently, he was a member of a special three-person radiological emergency assistance team that was invited to Japan in response to the March 2011 earthquake-tsunami disaster and the accident at the Fukushima Daiichi nuclear plant. While on the ground, the team exchanged information with Japanese counterparts and provided training to more than 1,100 hospital and healthcare professionals and emergency responders. In 2005, Dr. Becker was elected to the National Council on Radiation Protection and Measurements, where he currently serves on PAC 3 (Nuclear and Radiological Security and Safety) and PAC 7 (Radiation Education, Risk Communication, Outreach, and Policy). In 2010, he was named a G. William Morgan Lecturer by the Health Physics Society of the United States, and early in 2012 he was named to the National Thought Leader Advisory Council of the National Public Health Information Coalition. In September 2012, Dr. Becker was appointed by President Barack Obama to serve on the U.S. Nuclear Waste Technical Review Board. Dr. Becker holds a B.A. from George Washington University, an M.A. from Columbia University, and a Ph.D. from Bryn Mawr College. He also was a Kreitman Scholar at Ben-Gurion University of the Negev in Israel and a Visiting Fellow at the Japan Emergency Medicine Foundation and National Hospital Tokyo Disaster Medical Center.

Andre Bouville, Ph.D., was head of the Radiation Dosimetry Unit of the Radiation Epidemiology Branch of the National Cancer Institute (NCI) until his retirement at the end of 2010. He joined NCI in 1984, where, first as an expert and then as a senior radiation physicist, he has been involved in the estimation of radiation doses resulting from radioactive fallout from atmospheric nuclear weapons tests and from the Chernobyl accident. From 1972 to 1984, Dr. Bouville was employed in France by the French Institute for Radiological Protection and Nuclear Safety (IRSN) where he contributed to a number of environmental and dosimetric studies related to nuclear facilities. He obtained his Ph.D. in physics at the University Paul-Sabatier in Toulouse in 1970. Dr. Bouville was a member of Committee 2 (doses from radiation exposure) of the International Commission on Radiological Protection (ICRP) from 1989 to 2009, is a Distinguished Emeritus Member of the National Council on Radiation Protection and Measurements (NCRP), and a Lifetime Associate of the National Academy of Sciences. He was scientific secretary of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) from 1970 to 1972 and remained associated with that committee as a consultant until 2000. He also served as a member of the National Research Council's committee on Analysis of Cancer Risks in Populations near Nuclear Facilities: Phase 1.

Jean D. Brender, Ph.D., is a professor of epidemiology at the Texas A&M School of Public Health and served as associate dean for research during 2009-2014. Her main research interests include epidemiology of birth defects, prenatal environmental and occupational exposures and adverse reproductive outcomes, adverse health effects associated with residential proximity to industrial emissions and hazardous waste sites, and application of epidemiologic methods to clinical studies. She has 16 years of experience serving on institutional review boards—10 years on the Texas Department of Health board and 6 years on the Texas A&M University board. Dr. Brender has held consultancy positions with the Agency for Toxic Substances and Disease Registry. She holds a Ph.D. in epidemiology from University of Washington and an M.N. and B.S.N in nursing from the University of Washington and Whitworth University respectively. She is a fellow of the American College of Epidemiology.

Christie R. Eheman, Ph.D., has been chief of the Cancer Surveillance Branch at the Centers for Disease Control and Prevention (CDC) for 6 years where she oversees the funding as well as technical support and requirements for the National Program of Cancer Registries. Over the last 13 years as a cancer epidemiologist within the Division of Cancer Prevention and Control (DCPC), she has published studies related to breast, ovarian, uterine, and lung cancers. She is currently engaged in analyses of treatment patterns for colon and breast cancer. Prior to joining DCPC, Dr. Eheman focused on environmental exposures to radiation within the National Center for Environmental Health, CDC, where she was involved in assessing the risks associated with indoor radon, contaminated waste sites, and historic releases from Department of Energy sites. Since starting work at CDC in 1984, she has published on occupational exposures to indoor radon, on radon testing behaviors, and on the potential health consequences from nuclear reactor incidents. Dr. Eheman earned an M.S. in health physics from the Georgia Institute of Technology and a Ph.D. in epidemiology from Emory University. She is currently the CDC representative to the Executive Committee of the American Joint Committee on Cancer; serves on the Immunization Information Systems' Executive Board for the National Center for Immunization and Respiratory Diseases, which provide advice on priorities for the immunization registry; and serves on multiple cancer registry work groups and steering committees.

R. William Field, Ph.D., is a professor in the Department of Occupational and Environmental Health and in the Department of Epidemiology at the University of Iowa's College of Public Health. He is also a professor of toxicology and health informatics within the graduate college at the University of Iowa. In addition, he serves as director of the Occupational Epidemiology Training Program at Heartland Center for Occupational Health and Safety, funded by the National Institute for Occupational Safety and Health. He also serves as director of the Pulmonary Outcomes Cluster at the University of Iowa Environmental Health Sciences Research Center, funded by the National Institute of Environmental Health Sciences. He is a member of the U.S. Environmental Protection Agency's Science Advisory Board and currently chair of the board's Radiation Advisory Committee. He was appointed by President Obama in 2009 to the Advisory Board on Radiation and Worker Health. Dr. Field has been active in numerous national and international collaborative radiation-related epidemiological projects and has served on several previous National Academy of Sciences committees. Dr. Field received his Ph.D. in preventive medicine from the College of Medicine at the University of Iowa. He is a fellow of the American College of Epidemiology.

Daniel O. Stram, Ph.D., is professor in the Department of Preventive Medicine at the Keck School of Medicine of the University of Southern California. He received his Ph.D. in statistics from Temple University in 1983 and served as a postdoctoral fellow in the Biostatistics Department of the Harvard School of Public Health from 1984 to 1986. From 1986 to 1989, he was a research associate at the Radiation Effects Research Foundation in Hiroshima, Japan. Dr. Stram's main areas of research are in the statistical problems that arise in the design, analysis, and interpretation of epidemiological studies of cancer and other diseases. His work on radiation epidemiology studies includes helping to characterize the statistical nature of errors in dose estimates for the atomic bomb survivor study; developing a multilevel variance components model for the dosimetry used in the Colorado Plateau uranium miners cohort for the purpose of better understanding dose and dose rate effects in those data; and characterizing study power and sample size issues in epidemiologic studies in which a complex dosimetry system is used to estimate radiation dose. Besides the field of radiation epidemiology, his past and current research has focused on statistical issues relevant to clinical trials of treatment for pediatric cancer, nutritional epidemiology studies, and to studies of the genetics of complex diseases. He is an elected fellow of the American Statistical Association and has authored or coauthored over 200 peer-reviewed articles. He also served as a member of the National Research Council's committee on Analysis of Cancer Risks in Populations near Nuclear Facilities: Phase 1.

Margot Tirmarche, Ph.D., was appointed commissioner of the Nuclear Safety Authority of France in 2012. Prior to that she was director of scientific assessment at the Institute of Radiation Protection and Nuclear Safety (IRSN). She was the chief of the laboratory of epidemiology at IRSN for the period 1999-2008 and an epidemiologist in the same laboratory since 1980. She has a scientific background (Ph.D. equivalent) in biology and genetics, completed by specific diploma at the Medical University of Paris (Paris XI), related to epidemiology and oncology. During

the period 1975-1979, she worked at the Institute of Cancer in Villejuif in charge of the French coordination of a case-control study initiated by the National Cancer Institute (NCI), aiming toward a joint American-European analysis of lung cancer risk and tobacco consumption in different countries. She started in the radiation epidemiology field in 1980 and was in charge of the first cohort study in this field in France (uranium miners cohort). She conducted and coordinated several epidemiologic studies in relation to low chronic radiation exposure of various types: alpha exposure (radon decay exposure), external exposure (occupational cohorts), post-Chernobyl studies, and studies in the Urals. She also coordinated several multinational European contracts in the field of radiation epidemiology. She is a member of the French delegation at the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), contributing to recently published reports on radon and on Chernobyl effects. She is also a member of Committee 1 (radiation effects) of the International Commission on Radiological Protection (ICRP), where she is presently in charge of a working group that is analyzing cancer risk linked to alpha emitters (radon decay, uranium, plutonium). She is also an expert of the World Health Organization. Dr. Tirmarche also served as a member of the National Research Council's Committee on Analysis of Cancer Risks in Populations near Nuclear Facilities: Phase 1.

Jonathan C. Wakefield, Ph.D., has been professor in the Departments of Statistics and Biostatistics in the University of Washington since 2002. He was chair of the Statistics Department from 2009 to 2011. Over the past 20 years, Dr. Wakefield's main research focus has been on spatial epidemiology and in particular on methodological issues relating to ecologic studies. More recently he has been interested in the analysis of infectious disease data and on data arising from complex sampling designs. He has authored or coauthored around a 100 articles and published the book *Bayesian and Frequentist Regression Methods*. Dr. Wakefield received a Ph.D. in statistics from Nottingham University, UK. He is a fellow of the American Statistical Association and recipient of the Guy Medal in Bronze from the Royal Statistical Society.

STAFF

Ourania (Rania) Kosti, Ph.D., joined the staff of the Nuclear and Radiation Studies Board (NRSB) of the National Academy of Sciences in January 2011. Prior to her current appointment, she was a postdoctoral fellow at the Lombardi Comprehensive Cancer Center at Georgetown University Hospital in Washington, D.C., where she conducted research on biomarker development for early cancer detection using case-control epidemiologic study designs. She focused primarily on prostate, breast, and liver cancers and trying to identify those individuals who are at high risk of developing malignancies. Dr. Kosti also trained at the National Cancer Institute (NCI) (2005-2007). She received a B.Sc. in biochemistry from the University of Surrey, UK, an M.Sc. in molecular medicine from University College London, and a Ph.D in molecular endocrinology from St. Bartholomew's Hospital in London, UK. Dr. Kosti's interests within the NRSB focus on radiation health effects.

Jennifer (Jenny) Heimberg, Ph.D., has been at the National Academy of Sciences since 2011, working for NRSB. Within the NRSB, she has focused on nuclear security, nuclear detection capabilities, and environmental management issues. Dr. Heimberg has directed studies and workshops related to nuclear proliferation, nuclear terrorism, and the management of nuclear wastes. Prior to the NAS, she worked as a program manager at the Johns Hopkins University Applied Physics Laboratory (APL) for nearly 10 years. While at APL she established and grew its nuclear security program with the Department of Homeland Security's Domestic Nuclear Detection Office (DNDO). She received a B.S. in physics from Georgetown University, a B.S.E.E. from Catholic University, and a Ph.D. in physics from Northwestern University.

Appendix D

List of Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the Report Review Committee of the National Research Council. The purpose of this independent review is to provide candid and critical comments that will assist the National Research Council in making its published report as sound as possible and will ensure that this report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following individuals for their participation in the review of this report:

- Richard Clapp, University of Massachusetts Lowell, Lowell
- Dennis Deapen, University of Southern California, Los Angeles
- Roger Kasperson, Clark University (retired), Worcester, Massachusetts
- David Pawel, U.S. Environmental Protection Agency
- Roy Shore, Radiation Effects Research Foundation, Hiroshima, Japan
- Jane Simmonds, Health Protection Agency of the United Kingdom (retired), Oxon

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the contents of this report, nor did they see the final draft of the report before its release. The review of this report was overseen by Lynn Goldman, George Washington University, and Hedvig Hricak, Memorial Sloan Kettering Cancer Center. Appointed by the National Research Council, Drs. Goldman and Hricak were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were considered carefully. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

