

ANALYSIS OF CANCER RISKS IN POPULATIONS NEAR NUCLEAR FACILITIES: PHASE 2 PILOT PLANNING

In 2010, the National Academy of Sciences was asked by the U.S. Nuclear Regulatory Commission (U.S.NRC) to examine cancer risks in populations near the nuclear facilities it regulates (power plants and other nuclear sites). The National Academy of Sciences agreed to study the issue and the responsibility for the work was given to the National Academy of Sciences' Nuclear and Radiation Studies Board.

The process consists of two parts. The first part (Phase 1) was started in September 2010 and completed in May 2012. The goal of Phase 1 was to consider the various research methods that could be used (including the strengths and weaknesses of the different methods) and to then recommend the best scientific approaches to be used when examining cancer in populations near the nuclear facilities. (The Phase 1 report can be downloaded here: http://www.nap.edu/catalog.php?record_id=13388).

The goal of the second part of the process (Phase 2) is to carry out the recommendations from Phase 1 which are primarily related to establishing the feasibility of a nationwide study.

One of the main recommendations was that a pilot project involving seven nuclear facilities be conducted to determine whether the recommended scientific approaches can be done with the data (information) currently available or able to be located.

The National Academy of Sciences is currently planning the pilot project. Once the planning is completed in December, 2014, the pilot project will be carried out. (Carrying out the pilot project is subject to receipt of funding from the U.S.NRC.) Findings from the pilot project will inform whether a larger study of potentially all nuclear facilities in the United States is technically possible.

Because of the several phases and steps in the overall effort, for clarity of this Question and Answer (Q&A) document, the pilot project (involving seven facilities) is referred to as "the pilot" and the larger study of potentially all nuclear facilities in the U.S. is referred to as "the nationwide study." The term "study" is used to refer to the entire National Academy of Sciences activity requested by the U.S. NRC.

ABOUT THE STUDY

1. What is the purpose of the study?

The purpose of the study is to understand whether living near a nuclear facility (nuclear power plant or other nuclear facility) is linked with an increased risk of cancer.

2. Why is the study being carried out?

The study is being carried out at the request of the U.S. Nuclear Regulatory Commission (U.S.NRC) which needs current information to understand cancer risks around the nuclear facilities it regulates and to use those findings to inform the public.

3. Why is the study being carried out now?

The U.S. NRC is using the results from a 1990 National Cancer Institute study as its main information resource to inform the public about cancer risks around nuclear facilities. That study found overall that there is no increased risk in cancer mortality near the nuclear facilities that were studied. However, the National Cancer Institute study is over 20 years old. Since it was conducted, the list of nuclear facilities in the United States has changed and so have the characteristics of the populations that live near those facilities. In addition, the 1990 National Cancer Institute study had several research methods limitations that a new study could improve on. In particular, it utilized county-level information on cancer death (mortality) which makes it difficult to identify potential local effects around nuclear facilities. Cancer mortality is not the best indicator of risk because advances in cancer treatment have lowered mortality rates for many types of cancer. The National Cancer Institute study also did not estimate the radiation doses received by the studied populations.

4. Who is carrying out the study?

The National Academy of Sciences is carrying out the study. National Academy of Sciences conducts its studies by appointing committees of independent experts who are responsible for all technical aspects of the study; this includes study design, information gathering and analysis, and preparation of a report that provides the committee's findings, conclusions, and recommendations.

5. Have similar studies been carried out in other countries with nuclear facilities?

Studies of cancer risks in populations near nuclear facilities have been carried out in at least 12 countries: Belgium, Canada, Finland, France, Germany, Great Britain, Israel, Japan, Spain, Sweden, Switzerland, and the United States. Some of these studies have observed an association between residential proximity to nuclear facilities and increased risk of leukemia in children. However, investigators have been unable to link the increased risk in leukemia to radioactive releases from the facilities.

ABOUT THE NATIONAL ACADEMY OF SCIENCES

6. What is the National Academy of Sciences?

The National Academy of Sciences is a private, non-profit organization established by an Act of Congress, which was signed by President Abraham Lincoln in 1863. The National Academy of

Sciences provides independent, objective advice to the nation on matters related to science, technology, and medicine.

National Academy of Sciences produce about 200 reports per year on a variety of critical topics. The National Academies Press offers more than 4,000 titles in PDF format. All of these PDFs can be downloaded for free here: <http://www.nap.edu>.

7. How are the experts on National Academy of Sciences committees selected?

Members of the committees are chosen based on their knowledge and expertise in the critical areas needed to carry out a study. They are leading national and international experts who serve on the committees as volunteers. The National Academy of Sciences identifies these individuals by drawing upon a vast network of national and international contacts and resources.

8. Is the National Academy of Sciences' study process independent and objective?

The National Academy of Sciences have developed procedures for ensuring the quality and objectivity of its studies. The National Academy of Sciences work to avoid conflicts of interest and ensure representation of balanced views in the membership of its committees. Experts nominated to serve on a committee undergo a thorough process of conflict of interest and balance examination and are required to submit certain background information and information regarding conflicts of interest. The information is reviewed at several levels within the National Academy of Sciences. A provisional slate is approved by the leadership of the National Academy of Sciences and the names and short bios of the provisional slate are posted for public comment on the National Academy of Sciences website. Any issues raised during this thorough process of conflict of interest and balance examination are investigated and addressed and changes to the committee are proposed and finalized.

As a final check on the quality and objectivity of National Academy of Sciences studies, all National Academy of Sciences reports undergo a rigorous and independent external review by experts whose comments are provided anonymously to the committee members.

Experts serving on National Academy of Sciences committees and National Academy of Sciences report reviewers receive no compensation from the National Academy of Sciences.

ABOUT THE PILOT

9. What is a pilot and what is it intended to accomplish?

A pilot is a scientific tool that allows investigators to conduct a preliminary investigation before committing to a full-scale study. In this case, the purpose of the pilot is to test whether a nationwide study of cancer risks near nuclear facilities could be done using the study designs selected and the data (information) currently available or able to be located.

10. Why is the National Academy of Sciences conducting a pilot before the nationwide study?

Conducting a pilot was a recommendation of the National Academy of Sciences Phase 1 committee (The Phase 1 report can be downloaded here: http://www.nap.edu/catalog.php?record_id=13388). For the purpose of the pilot see response to question 9.

11. What nuclear facilities will be studied in the pilot?

Based on the Phase 1 report, seven nuclear facilities were chosen for the pilot (six nuclear power plants and one fuel-cycle facility). These are:

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

These facilities were chosen to represent the types of challenges the researchers are likely to encounter when conducting the study. If the pilot finds that a nationwide study is technically possible, additional facilities will be examined.

12. Why were these facilities chosen for the pilot?

These facilities were chosen to represent the types of challenges the researchers are likely to encounter when conducting the study. They include both nuclear power plants and a nuclear fuel cycle facility regulated by the U.S.NRC—a uranium fuel fabrication facility was selected for the latter. Among the nuclear power plants, the selected plants feature different nuclear power plant reactor designs, years of operation, and current operational statuses. For example, the reactors in three of the nuclear power plants are Boiling Water Reactors (Dresden, Oyster Creek, Big Rock Point) and three are Pressurized Water Reactors (Millstone, Haddam Neck, San Onofre). These plants started operation in the 1950s (Dresden), 1960s (Haddam Neck, Big Rock, San Onofre) and 1970s (Oyster Creek) with some reactors being added on the sites as late as in the 1980s (Millstone and San Onofre). Three of the selected plants currently operate (Dresden, Millstone, Oyster Creek) while the remaining are either decommissioned (Haddam Neck, Big Rock Point) or have permanently ceased operation (San Onofre).

In addition to the plant-specific characteristics that led to the selection of the pilot facilities, the states that contain the chosen facilities have performed differently with respect to tracking information on cancer occurrence or death and with their policies for sharing the information for research.

A pilot study of the chosen facilities and the states that contain these facilities will likely reveal some of the logistical difficulties and potential problems with accessing the required information to perform a study on cancer risks.

13. Why were other facilities not included in the pilot?

As this is a pilot, a small number of facilities was selected to test whether a nationwide study is technically possible. If a nationwide study is deemed technically possible, additional U.S.NRC-licensed facilities will be considered for examination.

14. Can I have my local nuclear facility included in the pilot?

No. The facilities for the pilot study have already been selected. See response to question 11.

ABOUT THE STUDY DESIGNS

15. What study designs will be used?

The Phase 1 of the study, which took 18 months to complete, focused on the examination of appropriate study designs for carrying out the study. The committee tasked with carrying out the Phase 1 and issuing the resulting report (the report can be accessed here: http://www.nap.edu/catalog.php?record_id=13388) consisted of experts from various fields with in-depth knowledge on the different scientific methods.

The Phase 1 committee recommended using two study designs: a population-based study (also called ecologic) and a case-control study.

The ecologic study will describe cancer rates (both cancer incidence and mortality) in populations living in census tracts within approximately 50 kilometers (30 miles) of the nuclear facilities. A study zone of this size would incorporate both the most potentially exposed as well as essentially unexposed populations to be used for comparison purposes. The study will examine all relatively common cancer types at all ages for the operational histories of those facilities to the extent allowed by available data.

The case-control study will describe whether children (younger than 15 years of age) born near the nuclear facilities are at higher risk of developing cancer compared to those who were born further away. The case-control study of childhood cancers could provide a more focused assessment of the association of these cancers in relation to early life exposure to radiation.

16. Why were these study designs chosen?

The Phase 1 report recommended the 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.

17. What questions will the study answer?

The recommended ecologic and case-control studies will aim to answer different questions.

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?

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?

18. What kinds of cancers are being examined in the study? Why?

The list of cancers considered is different in the two study designs tested in the pilot.

The ecologic study will examine all relatively common cancer types including cancers that are not considered to be caused by radiation. The ecologic study will provide a broad investigation of both cancer incidence and mortality at all age groups.

The case-control study will examine all pediatric cancers with emphasis given to leukemia and brain cancer. The case-control study of pediatric cancers will provide a more focused investigation of these cancers in relation to early life exposure to radiation.

19. What age groups are being studied? Why?

The ecologic study will provide a broad investigation of both cancer incidence and mortality in all age groups. The case-control study will provide a more focused examination of the association of cancer in children (age 0-15 years) in relation to early life exposure to radiation.

There are several reasons why studies of cancer risks near nuclear facilities focus on children. For example:

- Children and fetuses, due to their rapidly dividing cells during development, are typically more sensitive to environmental effects, including radiation exposure, compared to adults.
- Pediatric cancers have been the focus of many studies, some of which identified increased risks of leukemia in children. Leukemia is recognized to be the "sentinel indicator" (an identifiable sign of a potential environmental health issue) for radiation effects, occurring within a shorter time following exposure (as early as 2-5 years) than for other cancers.

20. Will people living near the nuclear facilities be interviewed during the study?

No. People will not be interviewed during the study. Instead, the National Academy of Sciences and its contractors will make use of existing health information from cancer registries and vital statistics offices as well as existing information from other sources such as birth certificates and the U.S. census to conduct the study.

21. Why are two study designs being used?

The recommended ecologic and case-control studies each have a different focus: The ecologic study will provide a broad investigation of both cancer incidence and mortality over the operational histories of nuclear facilities to the extent allowed by available data. The analysis will be based on place of residence at time of cancer diagnosis or at time of death from cancer.

The case-control study of pediatric cancers will provide a more focused assessment of the association of pediatric cancers in relation to early life exposure to radiation during more recent operating periods of nuclear facilities. An analysis based on place and time of birth of the child may be considered more appropriate for capturing relevant exposures.

The recommended methods were chosen based on scientific merit, a preliminary analysis of their technical feasibility, and their ability to address public concerns about cancer risks near nuclear facilities. More details can be found in the Phase 1 report at: http://www.nap.edu/catalog.php?record_id=13388

22. What are the drawbacks or limitations of these study designs?

One limitation of these study designs is that doses received by the populations near the facilities are estimated based on an assumption that these populations lived in the same location until they developed cancer or died of cancer. This is an unavoidable assumption because there is no centralized source of information for residential history of people in the United States.

A second limitation is that there is incomplete information available about lifestyle habits (e.g., smoking) of the populations living near nuclear facilities. Without this information it is not possible to conclude that any observed increases in occurrence of cancer, for example lung cancer, that appear to correspond to estimated radiation exposure, are not likely due to the influence of smoking or other such risk factors. There is also no centralized source of information for radiation doses received from other sources such as medical procedures.

A third limitation relates to interpretation of the results. Because of the assumptions and incomplete information mentioned above, results from the study will be uncertain. Therefore, interpreting and communicating what these results mean for the health of the populations that live near the nuclear facilities will be difficult.

23. What if the two designs being used for the study come to different conclusions?

The two study designs are intended to address different questions using different approaches (see response to question 21). It is possible that they will come to different conclusions. If this happens, a careful examination of the possible reasons the studies come to different conclusions will be needed.

24. What is dosimetry?

Dosimetry is the assessment of exposure of humans to ionizing radiation. In the context of this study, dosimetry involves the assessment of exposures of populations living near nuclear facilities to ionizing radiation released during the routine operations of those facilities.

25. What is epidemiology?

Epidemiology is the scientific study of health and disease in populations. It involves describing patterns of disease occurrence and finding the causes of disease and poor health, testing interventions to reduce disease and improve health, and assessing the consequences of interventions.

MEASUREMENTS

26. Will the pilot make new measurements of radioactive material releases from nuclear facilities?

No. The pilot will not make new measurements of radioactive material releases from nuclear facilities. It will make use of previously collected data on radioactive releases from the facilities, the state, and other entities.

27. What radioactive material release data will be considered in the pilot?

The pilot will consider all radioactive material releases reported by the facilities, both airborne and liquid. The study will also examine radiation measurements in the environment reported by the nuclear facilities, states, and other entities.

28. Will the pilot study consider different ways in which someone could be exposed to radiation from nuclear facilities?

Yes. The pilot will examine different “pathways” through which someone could be exposed to radiation releases from nuclear facilities. These pathways include external exposures to radiation, for example from radioactive gases released by a nuclear facility, as well as internal exposures from ingestion and inhalation of radioactive materials released by the facilities.

29. Where do the data come from? Who gathered/provided them?

The data that will be used in the pilot have been collected by each nuclear facility and reported to the U.S.NRC. Each facility is legally required to monitor and routinely report the amount of radioactivity that is released into the environment during facility operation and also during decommissioning.

The study will also examine radiation measurements in the environment reported by the states and other entities.

30. How will the National Academy of Sciences make sure that the radiation release data used in the pilot study are accurate?

The National Academy of Sciences will explore ways to validate the measurements performed by the nuclear facilities for accuracy. One possible way is to examine measurements made by the states where the nuclear facilities are located and compare them to those reported by the nuclear facilities.

31. Will the study determine whether all radiation releases from nuclear facilities have been recorded and reported?

The possibility of unrecorded releases will be considered for each nuclear facility separately.

PROCEDURES FOR CARRYING OUT THE PILOT

32. How will the pilot be carried out?

The pilot will be carried out by outside investigators (contractors) selected by the National Academy of Sciences. Their work will be carefully overseen by a National Academy of Sciences expert committee.

33. How will the National Academy of Sciences oversee the work of the contractors to ensure it is of high quality?

The National Academy of Sciences will assemble a committee of experts to oversee the work carried out by the contractors. This will involve regular meetings of the contractors and the National Academy of Sciences expert committee to review progress on the pilot, provide advice on methodological approaches, and make specific recommendations on execution of the study.

At the conclusion of the pilot the National Academy of Sciences committee will write a report describing the study findings and recommendations.

34. How will the contractors be chosen?

The contractors will be chosen based on the following criteria: expertise in and experience with relevant epidemiologic and dosimetric methods; capability to carry out the work within the requested timeframe; cost effectiveness; and ability to carry out the work in a fair and objective manner.

35. How long will the pilot take?

The total length of the pilot has not yet been determined. Once this is determined, the information will be posted on our website.

36. Who is paying for the pilot?

The pilot will be sponsored by the U.S. NRC.

37. Will the pilot be independent? Can the sponsor change the results?

The pilot is being carried out by the National Academy of Sciences, which is an independent institution. The sponsor has no control over the direction of the pilot and cannot change the results or suggest changes to the presentation of the results.

38. What if the pilot shows that a cancer risk assessment is not technically feasible?

If the pilot shows that a nationwide study is not technically feasible then the nationwide study will not move forward.

39. What will be done with the data and other documents generated by the study?

Information related to radioactive releases from the nuclear power plants is public information and can be accessed by the public. Individual information on cancer occurrence or death from cancer provided by the states, however, is considered protected health information and cannot be shared with the public due to regulations for the protection of personal health information. To the extent permissible, summaries of data without personal identifiers will be provided in the comprehensive final report authored by the National Academy of Sciences committee that oversees the pilot.

40. What will be done with the results of the study?

The results of the study will be published in a report authored by the study committee. This report will be presented to the project sponsor (U.S. NRC) and made available to the public without restriction.

PUBLIC PARTICIPATION

41. How can the public provide input?

Members of the public are encouraged to provide input to the National Academy of Sciences and the study committee on issues related to the study via the project email (crs@nas.edu) or in person at committee meetings. Questions may also be directed to the project email.

42. Can members of the public visit a nuclear site?

Members of the public interested in visiting a nuclear site will need to contact the site directly. National Academy of Sciences does not facilitate site visits.

43. Can members of the public attend committee information-gathering meetings?

Members of the public are welcome to attend any of the committee's information-gathering meetings. National Academy of Sciences provides public notice of these meetings. Anyone needing information about the dates, times, and locations of the meetings should contact us at the study email at crs@nas.edu. Members of the public can also go to the study website (<http://nas-sites.org/cancerriskstudy/>) to sign up for periodic updates and meeting announcements.

44. Sometimes organizations or individuals give technical presentations at the committee's information-gathering meetings. Are these organizations or individuals part of the committee?

The National Academy of Sciences committee is reaching out to a broad range of individuals and groups to obtain their insights on issues related to the study. This input is valuable. However, these people, whether representing their own organizations or speaking as individuals, are not part of the committee, nor do they speak for or represent the committee. The National Academy of Sciences committee is an independent body.

45. Can members of the public make comments at committee meetings?

Yes. Time is allocated during each information-gathering meeting for members of the public to make comments. Members of the public can also submit written comments to our project email (crs@nas.edu) at any time during the study.

46. Can members of the public send a letter to the committee or submit material for the committee to review?

Yes. Members of the public can submit written comments to the project email (crs@nas.edu). Members of the public can also submit material that they wish to bring to the committee's attention. Any comment or submission for the committee will be placed in the public access file for the study.

47. Can members of the public attend the committee's working sessions?

Only committee members, staff, and other agents of the National Academy of Sciences are allowed to attend committee working sessions. Committee working sessions are not open to members of the public, stakeholders, project sponsors, or others so that committee members can hold discussions and draft its report free from outside influences. However, summaries of the topics discussed, documents distributed, and committee members present during these working sessions are posted on the National Academy of Sciences webpage within 10 days following each working session.

48. Is there a webpage for the study?

Yes. You can find study background information and current updates at:
<http://nas-sites.org/cancerriskstudy/>

49. Will the public have opportunities to follow the progress of the pilot?

Yes. The National Academy of Sciences sends out updates through the project listserv. If you'd like to join the listserv, please send an email to crs@nas.edu. Information about the project is also available on the project webpage: <http://nas-sites.org/cancerriskstudy/>