

# **POLICY ISSUE**

## **(Information)**

October 5, 2012

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FOR: The Commissioners

FROM: Brian W. Sheron, Director  
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SUBJECT: NEXT STEPS FOR THE ANALYSIS OF CANCER RISKS IN  
POPULATIONS NEAR NUCLEAR FACILITIES STUDY

### PURPOSE:

The purpose of this paper is to inform the Commission of staff plans for the next steps of the Nuclear Regulatory Commission (NRC)-sponsored Analysis of Cancer Risks in Populations near Nuclear Facilities study.

### SUMMARY:

In April 2010, the NRC staff requested the National Academy of Sciences (NAS) to perform a study on cancer mortality and incidence risks in populations living near NRC-licensed facilities to update the 1990 National Cancer Institute (NCI) report on "Cancer Risks in Populations near Nuclear Facilities." The study was divided into two phases. In Phase 1, NAS explored the feasibility of conducting an updated study by developing modern methods to perform the analysis. The staff has reviewed the results of the Phase 1 study and the NAS recommendations for the next phase. The staff's next step will be to proceed with the NAS-recommended approach to determine the feasibility of the Phase 1 methods through pilot studies at seven sites recommended by the NAS committee: Dresden in Illinois, Millstone in Connecticut, Oyster Creek in New Jersey, Haddam Neck (decommissioned) in Connecticut, Big Rock Point (decommissioned) in Michigan, San Onofre in California, and Nuclear Fuel Services in Tennessee. Upon completion of the pilot studies, NAS will comment whether further study is beneficial, and the NRC staff will determine whether to perform the studies at all NRC-licensed facilities (i.e., balance of operating nuclear power plants and fuel-cycle facilities).

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BACKGROUND:

Each commercial nuclear power plant and fuel cycle facility that the NRC regulates is authorized to release radioactive materials to the environment as specified in the regulations and licensing documents, in compliance with dose limits for members of the public and concentration limits for liquid and gaseous effluent releases. For nuclear power plants, NRC regulations and licenses require each licensee to establish and maintain a program for monitoring radioactive effluents (Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50.34a, "Design Objectives for Equipment to Control Releases of Radioactive Material in Effluents – Nuclear Power Reactors," 10 CFR Part 50.36a, "Technical Specifications on Effluents from Nuclear Power Reactors," and 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation To Meet the Criterion 'As Low as Is Reasonably Achievable,' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents"). NRC regulations in 10 CFR Part 50.36a require licensees to report these effluents in an annual radioactive effluent release report. Regulations for fuel cycle facilities effluent reporting are found in 10 CFR Part 70.59, "Effluent Monitoring Reporting Requirements," and 10 CFR Part 40.65, "Effluent Monitoring Reporting Requirements." The staff has reviewed these reports and has concluded that offsite doses to individual members of the public are a small fraction of the 10 CFR Part 20 "Standards For Protection Against Radiation" limits specified in 10 CFR 20.1301(a) and (e). The offsite dose to the highest exposed member of the public is also generally less than 1% of the amount of radiation the average U.S. citizen receives in a year from all background sources. Nonetheless, some stakeholders have expressed recurrent concerns about the potential effect of these releases on the health of residents living near nuclear facilities.

To help address these stakeholder concerns, the staff uses the 1990 National Cancer Institute (NCI) report and other more recent epidemiology<sup>1</sup> reports conducted by various State Health Departments when communicating on cancer mortality in populations near nuclear power facilities. The staff relies on credible health studies to augment its discussions about the NRC's robust regulatory programs to keep offsite doses as low as is reasonably achievable (ALARA) by providing public health information that directly applies to the health outcomes that are often of concern (i.e., cancer). However, the 1990 NCI report is now more than 20 years old, and more modern analysis methods, combined with up-to-date information sources, will provide contemporary cancer information in current populations living near NRC-licensed nuclear facilities. As a result, the NRC program office staff sent a user-need request to the Office of Nuclear Regulatory Research to update the NCI study. These concerns are not new or unique to the United States. Since 2008, France, Germany, Great Britain, Spain, and Switzerland have all conducted epidemiology studies of populations near nuclear facilities within their borders to address public health concerns.

Accordingly, the staff chose to provide a grant to NAS to perform the study. NAS agreed to take a two-phase approach. In Phase 1, NAS performed a feasibility study that developed approaches to evaluate cancer risks in populations living near nuclear power and fuel cycle facilities licensed by the NRC. NAS developed methodological approaches for assessing offsite radiation dose and methodological approaches for assessing cancer epidemiology. For Phase 2, NAS would perform the cancer risk assessment using the methods developed in Phase 1 at all NRC-licensed facilities. Because these are new methods with expected low statistical

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<sup>1</sup> Epidemiology is the study of the distribution of illness, injury, disability, and death within a population.

power<sup>2</sup> and different cancer data quality from state-to state, NAS recommends an interim step between Phase 1 and 2. This step is for NAS to perform pilot studies to evaluate the feasibility of the Phase 1 methods before staff decides on proceeding with Phase 2 for the balance of the operating nuclear power plants and fuel cycle facilities.

### DISCUSSION:

The NAS established a twenty-member Phase 1 committee with expertise in biostatistics, contaminant transport, environmental exposure monitoring, epidemiology, medicine, public health, radiation dosimetry, radiobiology, social science and risk communication, and toxicology. The committee in its “Analysis of Cancer Risk in Populations near Nuclear Facilities—Phase 1” report (ADAMS Accession No.ML12254A165), provided the NRC with three findings and three recommendations for staff consideration.

#### *NAS Findings and Recommendations*

The committee’s first finding identified four key limitations for performing epidemiological studies around NRC-licensed facilities:

- uneven availability and quality of data on cancer mortality and incidence at geographic levels smaller than a county;
- uneven availability and quality of data on nuclear facility effluent releases based on an initial review of a limited set of records;
- inability to reliably capture information on population mobility, risk factors, and potential confounding factors (e.g. smoking, diet, or other lifestyle factors that would affect cancer risk); and
- low expected statistical power.

In its second finding, the committee concluded there are several study designs that could be used to perform a cancer risk assessment around nuclear facilities. Interestingly, the committee considered a non-epidemiological approach. They contemplated using a cancer risk projection model that uses cancer risk values from other radiation exposed populations (e.g., Japanese atomic bomb survivors) and dose information for the populations around nuclear facilities to calculate their cancer risk. However, the committee rejected this as a recommended approach because it predicted public credibility challenges as the cancer risk assessment would be based on the same effluent and dose data that the staff uses to confirm compliance with NRC regulations. The use of this data has presented challenges when used in communicating levels of risk to the public.

The committee’s third finding concluded that facility data on radioactive effluent release, direct exposure, and meteorology can be used to obtain estimates of annual variations in dose as a function of distance and direction from nuclear facilities. This finding appears to challenge the first finding on the uneven availability and quality of data on nuclear facility effluent releases. However, the committee believed there was enough quality data to perform dose estimates to

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<sup>2</sup> Statistical power is typically determined before the study starts and tells the researcher how big of a sample size is needed to detect a certain level of a health effect.

support the epidemiology studies. Each facility would need to be individually evaluated to determine the quality and availability of data since they vary in designs, operating histories, and location. To perform the dose assessment, existing computer models could be used to estimate absorbed tissue doses from airborne and waterborne radioactive effluent releases. Finally, the committee concluded that the environmental monitoring data have limited usefulness for estimating absorbed doses from radioactive effluent releases because most of the results are below laboratory detection limits.

The committee's first recommendation to the NRC is to perform two types of epidemiology studies—an ecologic study of multiple cancer types of populations living near nuclear facilities and a case-control study of cancers in children born near nuclear facilities<sup>3</sup>. These two study designs combine dose assessments with the ability to analyze many different cancer types, while also specifically focusing on children's cancer in the case-control study.

In its second recommendation, the committee proposes to conduct pilot studies at seven sites to determine the feasibility of performing the study designs on a larger scale. This information would be used to estimate the required time and resources should the study be expanded to Phase 2.

NAS's suggested sites for the pilot study are:

- Dresden Nuclear Power Station, Morris, IL (2 BWRs, 1 BWR shutdown)
- Millstone Power Station, Waterford, CT (2 PWRs, 1 BWR shutdown)
- Oyster Creek Nuclear Generating Station, Forked River, NJ (1 BWR)
- Haddam Neck (decommissioned), Haddam Neck, CT (1 PWR)
- Big Rock Point Nuclear Power Plant (decommissioned), Charlevoix, MI (1 BWR)
- San Onofre Nuclear Generating Station, San Clemente, CA (2 PWRs, 1 PWR shutdown)
- Nuclear Fuel Services, Erwin, TN (operating uranium fuel fabrication facility)

The committee selected these sites because they provide a good sampling of facilities in six States with different operating histories, population sizes, and levels of complexity in data retrieval from the State cancer registries. The State cancer registries for these sites are at different levels of maturation and have different approval protocols for accessing the cancer incidence and mortality data needed for the assessment.

In its third recommendation, the committee stated that a plan for communicating with interested parties and engagement should be developed before the initiation of data gathering and analysis for these studies. It also emphasized the importance of early involvement of interested parties when conducting the next phase. This includes providing avenues for engagement similar to that provided during Phase 1 by allowing members of the public to speak at committee meetings, creating a study e-mail list to inform interested parties of study status and forthcoming events, and establishing a study Web page.

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<sup>3</sup> The ecologic study design uses a geographical area as the unit of observation (e.g., census tract, county, ZIP Code) and uses an aggregate analysis that looks at a study factor (exposure) and an outcome factor (disease or death) measured in the geographical area at the same time. This study can show possible associations between exposure and disease. The case-control study design compares the prevalence of risk factors or exposures in a series of diseased study subjects (cases) with the prevalence of risk factors or exposures in a series of disease-free study subjects (controls).

Along with the findings and recommendations, the committee provided in its report a comprehensive review of the issues and challenges of performing epidemiology studies around nuclear facilities. The report identified one of the biggest challenges as the inability of the recommended study designs to detect health effects at the very low offsite radiation doses to members of the public from NRC-licensed facilities. The committee opted not to calculate the sample sizes needed to detect health effects at the low offsite doses from these facilities (dose equivalents < 0.01 millisieverts (mSv) per year or 1 millirems (mrem) per year) because, as stated in the report, "...the numbers of exposed persons required to find a possible association would be truly enormous" (i.e., > hundreds of millions). The committee used an alternative method to calculate sample size.

#### *Public Comments on NAS Phase 1 Report*

NAS solicited comments on the Phase 1 report for a 2-month public review period. The intent of the review period was to provide NAS feedback on stakeholder views of the proposed methods assuming the NRC decided to proceed with the next phase. The comments were not intended to change the committee's report.

NAS received 74 comments. The sources of comments varied from individual members of the public (73 percent), nongovernment organizations (NGOs) (16 percent), professional societies and industry organizations (4 percent), universities (4 percent) and State and tribal governments (3 percent).

One professional society and two industry organizations provided comments to NAS on the Phase 1 report. These organizations included the Health Physics Society (HPS), the Nuclear Energy Institute (NEI), and the Energy and Power Research Institute (EPRI). All three respondents complimented the Phase 1 study committee in its effort. HPS and NEI emphasized the limitations stated in the Phase 1 report and recommended that the NRC not proceed with the pilot studies. HPS, NEI, and EPRI all expressed concerns that the proposed pilot studies, with its significant limitations, would be very expensive and of limited usefulness because of its low statistical power.

A majority of the comments (59 percent or 44 comments) favorably endorsed and encouraged the NRC to proceed with the pilot studies. Another 18 percent of the comments (13) recommended that the NRC not proceed with the pilot studies based on similar reasoning of HPS and NEI. Finally, 23 percent of the comments (17) did not provide a recommendation either way on whether the NRC should proceed with the next steps.

#### *Staff Evaluation of Findings and Recommendations*

The staff did not agree with NAS' first finding pertaining to the uneven availability and lack of quality of data on nuclear facility effluent releases. The NAS staff indicated that some earlier records were difficult to find, and when found, the microfiche copies were difficult to read. The NRC requires licensees to maintain records and have a quality control program for radioactive effluents and environmental monitoring programs, which the agency routinely inspects. The staff believes these monitoring programs are of good quality, and the staff is confident that a complete set of effluent data is available for licensed facilities (and decommissioned sites). For early operating histories, some, if not most of the data may be on microfilm or microfiche, while for recent operational histories, the data are kept in more easily retrievable electronic files and databases. As a result, it may take time to retrieve the needed information, but the staff expects that all supporting data on radioactive effluent releases are available in some form.

The staff concurs with the committee's recommended sites. They provide a representative mix of facilities that would allow for an informed decision regarding the time, resources, and technical complexities of expanding the study. Additionally, most of the cost for the pilot studies is in the initial establishment of a new study committee and set-up of the Phase 1 methods and software. The incremental cost for each additional facility in the pilot study was not estimated to be that significant in comparison to the information to be gained on the feasibility of this research.

The committee's decision to not calculate sample sizes based on actual off-site doses confirms the staff position that at the low offsite doses from these facilities, researchers would not expect to observe any increased cancer risks in the populations surrounding these facilities attributed to the regulated release of radioactive effluents. Nevertheless, the staff believes that despite these potential limitations and expected outcomes, the studies would be helpful to address public health concerns and are therefore still worthwhile to pursue. As recent international studies indicate, epidemiology studies can be an important tool for allaying public health concerns, even with these known limitations. Additionally, the committee assessed the feasibility of performing health studies around uranium recovery facilities, and it recommended not studying these sites because of the sparse populations involved.

#### CONCLUSION:

The NRC staff plans to proceed with the pilot studies at the seven sites identified above in the first quarter of fiscal year 2013 and to complete the feasibility portion of this research as recommended by NAS. The staff intends to determine whether the recommended study designs can be performed at reasonable cost and effort, and whether they provide useful information to discuss public health concerns with NRC stakeholders. Once the pilot studies are complete, the staff will determine if the agency should proceed with Phase 2. The staff has notified each applicable licensee that we intend to go forward with the pilot studies at their facilities. The staff expects there to be minimal burden to the licensee because NRC has the radioactive effluent data and the state governments have the cancer registry data. The pilot study licensees will be included in the NAS outreach plan and receive periodic updates as the study progresses.

#### RESOURCES:

The pilot study will take 2-3 years to complete and will cost approximately 2 million dollars. After the pilot study, staff will review the results, effort, and cost to determine if the study should be expanded to Phase 2. Based on this information, the staff budgeted \$1.4 million in fiscal year 2013 and will restack the 2014 budget to align with the final cost of the pilot and potential Phase 2 study. This will come from the operating reactor budget line if staff decides to pursue it. The staff will request additional funding beyond 2014, if needed, through the Planning, Budget, and Performance Management process.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

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