

POLICY ISSUE Information

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SECY-15-0104

FOR: The Commissioners

FROM: Mark A. Satorius
Executive Director for Operations

SUBJECT: ANALYSIS OF CANCER RISKS IN POPULATIONS NEAR NUCLEAR
FACILITIES STUDY

PURPOSE:

The purpose of this paper is to update the Commission on the study of cancer risks in populations near nuclear facilities.

BACKGROUND:

Each commercial nuclear power plant and fuel cycle facility that the Nuclear Regulatory Commission (NRC) regulates is authorized to release radioactive materials to the environment and expose the public and workers to radiation. These releases and exposures must comply with regulations and licensing documents, including dose limits for members of the public and concentration limits for liquid and gaseous effluent releases, as well as ensure doses are as low as reasonably achievable (ALARA). The staff has concluded that offsite doses to individual members of the public as a result of these routine releases are ALARA and a small fraction of the dose limits specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," specifically 10 CFR 20.1301(a) and (e). The offsite dose to the highest exposed member of the public is also generally less than 1 percent of the amount of radiation the average U.S. citizen receives in a year from all background and medical sources. Nonetheless, some stakeholders have continued to express concerns about the potential effect of these releases on the health of residents living near nuclear facilities.

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These concerns are not new or unique to the United States. Since 2008, Canada, France, Germany, Great Britain, Spain, and Switzerland have all conducted epidemiological studies near nuclear facilities within their borders to address public health concerns. These studies have generally found no association between facility operations and increased cancer risks to the public that are attributable to the releases or radiation exposure. For example, the German study initially found an association of increased childhood leukemia risk within 5 kilometers of the facilities. However, upon examination of the offsite exposures, the authors concluded the increased risk could not be explained by the releases from the facilities¹.

The NRC staff routinely interacts with stakeholders about concerns of elevated cancer risk from facility operations. Although the offsite releases and resultant doses to the public from routine facility operations are very low, communicating this very low risk can be a challenge. To help address these concerns, the staff has been using the 1990 National Cancer Institute (NCI) study, "Cancer in Populations Living near Nuclear Facilities." NCI still supports the original report and has a fact sheet on the study that is publicly available on their web site at: <http://dceg.cancer.gov/about/organization/programs-ebp/reb/fact-sheet-mortality-risk>; the fact sheet is also in the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML15035A630. The study was also published in the Journal of the American Medical Association in 1991². In addition, other more recent epidemiological reports have been conducted by various State health departments. The staff relies on credible health studies to augment its discussions about the NRC's regulatory programs to keep offsite doses ALARA by providing public health information that directly applies to the health outcomes that are often of concern (i.e., cancer).

The 1990 NCI report is now more than 25 years old and focused primarily on cancer mortality, with limited cancer incidence (i.e., occurrence of the disease) in two states. As a result, NRC staff decided in 2007 to update this report, including a study of incidence if feasible, that would allow the staff to evaluate and communicate more contemporary cancer information for populations living near NRC-licensed nuclear facilities. In July 2007, the Office of Nuclear Regulatory Research received a formal request from the Office of Nuclear Security and Incident Response (NSIR), with concurrences from the Office of Nuclear Reactor Regulation (NRR), the Office of New Reactors (NRO), the Office of Public Affairs (OPA), and Region I requesting an update to the NCI study. The staff originally requested NCI to provide the update. However, NCI was unable to support the study and indicated these types of studies were no longer in their research focus.

Therefore, the staff contracted with the National Academy of Sciences (NAS) to perform the update. In April 2010, the NRC requested NAS perform the update study on cancer risks in populations living near NRC-licensed facilities to update the 1990 NCI study. NRC and NAS decided to divide the study into phases. In Phase 1, NAS explored the feasibility of conducting an updated study by using more modern methods to perform the analysis. This was documented in the 2012 report, "Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase 1" (ADAMS Accession No. ML15035A132). The staff communicated the results of the Phase 1 study and the NAS recommendations for the second phase pilot studies

¹ Kaatsch P, et al. "Leukaemia in Young Children Living in the Vicinity of German Nuclear Power Plants," [International Journal of Cancer](#), 2008 Feb 15; 122(4):721-6.

² Jablon S, Hrubec Z, and Boice JD. "Cancer in Populations Living Near Nuclear Facilities: A Survey of Mortality and Incidence in Two States," *The Journal of the American Medical Association*, 1991 Mar 20; 265(11):1403-1408.

in SECY-12-0136, “Next Steps for the Analysis of Cancer Risks in Populations near Nuclear Facilities Study” (ADAMS Accession No. ML12249A121). In Phase 2, NAS proposed to conduct pilot studies to determine the ability to practically apply the Phase 1 methods at seven sites recommended by the NAS committee: Dresden (Illinois), Millstone (Connecticut), Oyster Creek (New Jersey), Haddam Neck (decommissioned; Connecticut), Big Rock Point (decommissioned; Michigan), San Onofre (California), and Nuclear Fuel Services (Tennessee). NAS 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. NAS specifically recommended the pilot study examine two study designs: (1) a population study of cancer diagnosis and mortality rates for multiple cancer types and all age groups, down to the census-tract level; and a (2) case control study of childhood cancers in children born within a fixed distance of a nuclear facility³. Upon completion of the proposed Phase 2 pilot studies, NAS planned to determine whether further study is practical on a nationwide scale, and the NRC would then determine whether to perform the studies at all NRC-licensed facilities (i.e., balance of operating nuclear power plants and fuel-cycle facilities).

NAS split the Phase 2 pilot study into a pilot planning project and a pilot execution project. In the pilot planning project NAS explored the availability of facility effluent records and access to the pilot study site cancer registries in the respective states. In addition, NAS solicited cost estimates from contractors to determine the actual costs of performing the pilot study. This is described in the NAS pilot planning report, “Analysis of Cancer Risks Near Nuclear Facilities: Phase 2 Pilot Planning” (ADAMS Accession No.: ML15035A135).

DISCUSSION:

NAS stated in the pilot planning report that the pilot studies are meant to determine the practicality of implementing the methods and study designs recommended in Phase 1. It emphasized that any data collected during the pilot study would 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. NAS also cautioned that any decision to proceed with a full scope study should be based solely on conclusions related to practicality and not on risk estimates.

NAS communicated to the staff that the execution phase of the pilot study would require significant time and resources to complete: 39 months and \$8 million. The staff estimates that it may take NAS 8 to 10 years to complete the pilot and the subsequent nation-wide studies before NRC has final cancer risk results to share with NRC stakeholders—the original intent of the project. That would possibly prolong the study to 2025, 15 years after the start of the project with NAS.

Given the NAS position regarding the limited usefulness of the pilot study results to draw conclusions about the risk associated with the pilot plants (or just as importantly, single facilities), the long duration and high cost of the pilot study, and the long duration of subsequent

³ The population-based study design uses a geographical area as the unit of observation (e.g., census tract as proposed by NAS, county as used in the 1990 NCI report, 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).

studies, the staff concluded that a more timely and less costly alternative to the NAS proposal should be considered. To accomplish this, the staff communicated its concerns to NAS. Staff requested that NAS focus on providing final results for the next phase of the study to shorten the study time. Specifically, staff asked NAS to focus on the Phase 1 recommended case-control study design and perform an analysis of a sample of facilities in the United States to draw statistically valid and generalizable results to the entire fleet. In response, NAS proposed that the pilot planning committee reconvene to examine our request for the alternate approach at an additional \$200,000 cost for a 9-month study. After the new review, NAS estimated another 50 months to complete the alternate approach at an uncertain cost.

While the staff was considering NAS' response, the President of the U.S. National Council on Radiation Protection and Measurements (NCRP) approached the staff about conducting an update to the 1990 NCI study. NCRP is an organization chartered by the U.S. Congress in 1964. The Charter of the Council (Public Law 88-376) states its objectives to include: collect, analyze, develop and disseminate in the public interest information and recommendations about (a) protection against radiation and (b) radiation measurements, quantities and units, particularly those concerned with radiation protection. The current President of NCRP was one of the original authors of the 1990 NCI study, and he has been following the staff activities with NAS with interest. NCRP indicated that it could update the 1990 NCI study report in 2 to 3 years and for approximately \$2.5 million (staff estimate). An update to the NCI study would be a more modest initiative. Instead of the NAS recommended two study designs, an NCI update would use the same methods used in the 1990 study—a countywide population-based study design, no dosimetry considerations, and limited cancer incidence information.

CONCLUSION:

After considering the approaches described above in the context of NRC's current and projected operating environment, the staff has decided to end the Cancer Study. The staff believes the NAS proposal is not timely and the costs are excessive. While the NCRP proposal is more modest in scope, and could be done faster and for significantly less cost than the NAS study, it continues to have the same limitations as the 1990 study (county-based and primarily examining only mortality rates). The staff will continue to monitor relevant health studies published by national and international experts and if warranted, revisit the need for an update to the Cancer Study. In addition, the staff will write a letter to the NAS by October 2015 describing the basis for the staff's conclusion to end the Cancer Study.

RESOURCES:

Resources are discussed in the enclosure, which is not publicly available.

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 paper for resources implications and has no objections.

/RA Michael F. Weber for/

Mark A. Satorius
Executive Director for Operations

Enclosure:
As stated

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