Executive Summary

Proposed Updated Study and EPRI Feedback Approach

The Nuclear Regulatory Commission (NRC), through the National Academy of Sciences (NAS), is updating the 1990 U.S. National Institutes of Health - National Cancer Institute (NCI) report, "Cancer in Populations Living Near Nuclear Facilities". The Electric Power Research Institute (EPRI) formed a committee of scientists and professionals in the fields of epidemiology, radiation biology, nuclear plant effluents, and environmental risk assessment to provide study design considerations to the NAS committee responsible for scoping the update to the 1990 NCI report. These technical considerations address the data challenges that exist, the statistical limitations inherent in this type of study, and provide key suggestions on epidemiological approaches that may facilitate meaningful study results.

Since the focus of the NAS study is on public exposures from normal operations of nuclear facilities- as opposed to public exposures from emergency operations or accident events of nuclear facilities- this report will also focus on the releases and health effects from routine plant operations.

Key Conclusions from Previous Studies

In the 1980s, the National Cancer Institute conducted an epidemiological study of cancer mortality risk in the populations around 52 nuclear power plants and 10 DOE nuclear facilities. The results of the study were published in a 1990, National Cancer Institute report and a 1991 Journal of the American Medical Association manuscript. The study concluded that deaths from cancer were not more frequent in the counties located near nuclear facilities as compared to control counties. Specifically the study found that "…if nuclear facilities posed a risk to neighboring populations, the risk was too small to be detected by a survey such as this one." [1]. In comparing childhood leukemia mortality in counties near nuclear facilities with leukemia mortality in the control counties, the relative risk (ratio of the standard mortality ratios) was 1.08 before plant start-up and 1.03 after start-up. For all ages the corresponding relative risks were 1.02 before and 0.98 after start-up. The authors point out that the study, although showing no effect on cancer rates of residing in a county with a nuclear facility, was limited by the correlational approach used and the large size of the counties. The authors also point out that at the time, the monitored emissions from nuclear facilities were less than 0.03 mSv (3 mrem) per year to the maximally exposed individual while natural background levels excluding radon exposure to the lung were about 1 mSv (100 mrem) per year.

Since the publication of the NCI report, several international studies have been undertaken, specifically in the United Kingdom [2–4], Germany [3, 5, 6], and France [7, 8]. Principal attention in these studies focused on childhood cancers, especially leukemias in children under age 5. Some of the studies measured total radiation exposures by including local terrain and climate information as well as nuclear power plant sources, with total exposures from nuclear power plant sources estimated at 1,000 to 100,000 times lower than from natural sources. Occasional clusters of cancer incidence have been observed within 5 km of nuclear facilities. Leukemia rate increases have also been observed near non-power generating stations as well, leading researchers to hypothesize other potential causes for the increase.

One hypothesis gaining acceptance is Kinlen's hypothesis of cancer effects from population mixing, which postulates that such cancer clusters reflect underlying shifts in local population distributions ("population mixing"). The effect of population mixing is not confined to populations associated with nuclear power facilities, and may be caused by the introduction of infectious agents into a sensitive population. These agents are thought to be capable of inducing leukemia in children [9, 10].

Inherent Difficulties in Conducting an Epidemiological Study Involving Small Radiation Exposures

Understanding exposure conditions in the study population is essential in the design of any epidemiology study. Because the public is already exposed to a wide range of natural and man-made radiological sources during a lifetime, epidemiology studies involving incremental dose from specific radiation sources are even more challenging. For example, current dose risk models (e.g. the linear no threshold (LNT) model proposed by BEIR VI) suggest that doses of about 0.25 mSv (~25 mrem) over one year will result in a small increase in the risk of cancer (about 0.00125%) compared to the current U.S. population cancer risk of about 41%. To appropriately quantify cancer risk, a study cohort of 10 million persons exposed to about 10 mSv (1,000 mrem) would be required [11, 12]. Since the maximum dose calculated at the site boundaries of nuclear power plants for the proposed epidemiological studies is much smaller (<0.25 mSv/yr or 25 mrem/year), the population required to quantify cancer risk needs to be very large, since the smaller the dose, the larger the study population needed to discern cancer risk.

An essential aspect in carrying out such an epidemiology study is to determine or estimate actual public dose from environmental concentrations and other potential sources of exposure [13]. Without dose information, ecological studies of persons exposed to low levels of radiation are not recommended [13]. Dose values reported by nuclear facilities should not be used as actual or estimated dose measurements to members of the public because the methodology, assumptions, and approach used for nuclear facilities do not result in representative exposures to any real individual or population and vary greatly across facilities. Additionally, in accordance with regulatory requirements and licenses, the dosimetry models and parameter values adopted by these nuclear facilities, are outdated (e.g. dose coefficients used are from ICRP Publication 2 [14] which was published in 1959). The NAS committee will need to develop a common methodology or approach for linking effluent activity measurements to public dose in order to carry out the proposed update. It is also critical that dose-rate and dose distribution effects are taken into account in these studies. The use of the proper Dose, Dose Rate Effectiveness Factor (DDREF), tissue weighting factors, and dose-distribution are all essential for realistic risk estimates. This is especially important when the dose and risk from internally deposited radioactive material is considered, since dose distribution and organ sensitivity are critical for each of the radionuclides considered.

Furthermore, the use of distance from the facility as a surrogate for dose is not an adequate substitution because higher exposures could occur in populations living many miles away from the nuclear facility, depending on the specific meteorology and associated land use scenario relevant to that nuclear facility.

Summary of Considerations for NRC/NAS Study

The NAS committee should consider the following points in designing their new study. Each point is elaborated upon in the full report.

Recognize that an epidemiological study based on small dose relative to annual background and medical exposures will increase the difficulty of providing a definitive answer on cancer risks in populations living near nuclear facilities in the U.S.

Develop an appropriate risk communication plan during Phase 1 of the study that identifies and explains these challenges and clearly articulate the study expectations and how the results will be used.

For any planned epidemiological study, closely coordinate the dosimetric efforts with the epidemiologic efforts and develop a comprehensive and consistent exposure assessment methodology for dose evaluation.

With respect to epidemiological studies:

- Plan and conduct nationwide epidemiological studies using the basic methodology of the 1990 NCI county-based study, evaluating cancer at all ages, both by mortality and incidence (to the extent that usable cancer registry information may now be available in the U.S.).
- Estimate actual dose for the study populations instead of using distance from the facility as a surrogate for dose.
- Plan and conduct an analytic study (perhaps a case-control design) regarding childhood cancer with special attention given to leukemia and non-Hodgkins lymphoma in children under age 5. Use full life-span child information (including in-utero) about family history, personal illnesses, siblings,

day-care use, places of residence, and possible exposures to radiation or environmental toxins. Evaluate confounding factors, such as the population mixing hypotheses, which may influence the outcomes of the epidemiological studies.

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Electric Power Research Institute
3420 Hillview Avenue, Palo Alto, California 94304-1338 • PO Box 10412, Palo Alto, California 94303-0813 USA
800.313.3774 • 650.855.2121 • askepri@epri.com • www.epri.com