

January 15, 2002

Dr. Jerry Brown
Radiation and Public Health Project
1630 W 22nd Street
Miami Beach, Florida 33140

Dear Dr. Brown:

The U.S. Nuclear Regulatory Commission (NRC) staff is responding to your comments made at the July 17, 2001, public meeting held by the NRC in Homestead, Florida, related to license renewal of the Turkey Point Nuclear Plant. Specifically, we are responding to the document you submitted at the meeting entitled "Comments on Draft Report and Submission of New Information" dated July 17, 2001, by the Radiation and Public Health Project (RPHP). The conclusions in this letter will appear in the Final Supplement to the Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants: Turkey Point Plant Units 3 and 4.

We recognize that RPHP and you have devoted substantial effort to study the environmental factors that contribute to cancer mortality and morbidity. We commend your dedication to public health and your desire to reduce the incidence of cancer. The NRC routinely seeks out new scientific information that might reveal health and safety concerns. After careful review of the data and comments you provided, we have concluded that your July 17, 2001, submittal does not, as you claim, establish a causal link between past operation of the Turkey Point Nuclear Plant and an increased incidence of childhood cancer in southern Dade County, Florida.

The staff bases its conclusion on a variety of factors and data which are summarized in the attachment to this letter. Much of the information in the attachment will be presented in the final Supplement 5 to the GEIS, which will be published shortly. The staff reached its conclusion that the operation of the Turkey Point Nuclear Plant is not responsible for elevated levels of childhood cancer due to the inadvertent or deliberate release of the radioactive isotope strontium 90 in the vicinity of the facility for the following reasons:

- The State of Florida determined through an independent study that there are no elevated levels of childhood cancer in the vicinity of the plant;
- Environmental monitoring by the State of Florida around the plant has not shown any elevated levels of strontium-90 in the environment attributed to plant operation;
- The licensee has not reported any significant releases of strontium-90 from the plant;
- No causal relationship has been established between the levels of strontium-90 being reported by the RPHP in children's deciduous (baby) teeth and childhood cancer;

- The study did not sample for strontium-89 and strontium-90 in the environment around the Turkey Point Nuclear Plant. Without the presence of strontium-89 in environmental samples around the plant, the study has failed to establish that any strontium-90 found in the environment is attributed to plant operation. Therefore, it is not reasonable for the study to conclude that any strontium-90 found in deciduous teeth can be attributed to plant operation;
- The study did not determine the dose history of any of the children that contributed deciduous teeth;
- Based on our review of the report, we could not determine that the study followed normal epidemiological and statistical practices, including the use of control populations and statistical significance testing.

Your comments also questioned the adequacy of current public and occupational radiation protection standards. NRC's regulatory limits for members of the public and the workforce are based on radiation protection recommendations of both international and national organizations. The attachment discusses how these standards are maintained in more detail.

We appreciate public interest in radiological health issues and the risks and benefits of continued operation of nuclear power facilities. We also appreciate independent studies of nuclear safety issues and the opportunities to inform the public about radiological safety standards. Nevertheless, the results of your studies have not provided compelling evidence that (1) the Turkey Point facility is releasing significant quantities of strontium-90, or (2) there are detectable levels of strontium-89 around the plant, or (3) there is a localized increase in childhood cancers in the vicinity of the facility that is linked to exposure of strontium-90, or any other isotope. The staff, therefore, concludes that the RPHP findings regarding the relationship between nuclear power plant operation and the incidence of childhood cancer are not warranted, there is no need for further research on this premise, and we do not intend to pursue this issue further.

If you have any questions regarding our evaluation or conclusions, please do not hesitate to contact Dr. Michael T. Masnik (301-415-1191) of my staff.

Sincerely,

Original Signed By: CI Grimes

Christopher I. Grimes, Program Director
License Renewal and Environmental Impacts
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Enclosure:
NRC Staff Response to Alleged Human Effects
in Miami-Dade County from Elevated Levels
of Strontium-90 in the Environment

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NRC Staff Response to Alleged Human Effects
in Miami-Dade County from Elevated Levels
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ENCLOSURE 1

NRC STAFF RESPONSE TO ALLEGED HUMAN HEALTH EFFECTS IN MIAMI-DADE COUNTY FROM ELEVATED LEVELS OF STRONTIUM-90 IN THE ENVIRONMENT

NRC Staff Response to Alleged Human Health Effects in Miami-Dade County from Elevated Levels of Strontium-90 in the Environment

Introduction

During the scoping and public comment period for the Supplemental Environmental Impact Statement (SEIS) for License Renewal for Turkey Point, Units 3 and 4 (NUREG-1437 draft Supplement 5 [NRC,2001]), there were a number of comments about the studies related to strontium-90 radiation levels in deciduous (baby) teeth and use of these studies as “in-body” measurements of radioactive materials. The commenters alleged that the source of the strontium-90 was the Turkey Point plant and that there are elevated rates of childhood leukemia and cancer in the Miami-Dade and surrounding areas.

In 2000, a report titled *Strontium-90 in Deciduous Teeth as a Factor in Early Childhood Cancer* was published (Gould et al. 2000) alleging that there was an increase in cancer incidence due to strontium-90 released from nuclear power facilities. Elevated levels of strontium-90 in deciduous teeth was claimed in the report as the evidence for the increase in childhood cancer. At the July 17, 2001 public meeting on Turkey Point license renewal held in Homestead, Florida the NRC staff was given written comments from the Radiation and Public Health Project (Mangano et al. 2001). The submittal again alleged a causal link between plant operation and childhood cancer, that Federal standards for protection of the public from radioactivity released from nuclear plants were inadequate, and that Miami-Dade County, plus four counties to its north, had one of the highest rates of childhood leukemia and cancer. Additionally the submittal contained a number of recommendations including requesting additional studies around Turkey Point.

As discussed below, the staff has reviewed this issue in detail and concludes that the claims by the Radiation and Public Health Project (RPHP) staff, who were the authors of the Gould report and who also provided comments on the draft SEIS, are not supported by the facts.

The staff has determined that the strontium-90 found in deciduous teeth in the vicinity of Turkey Point Units 3 and 4 is not due to releases from the Turkey Point Plant and that there is no increased incidence of childhood cancer in the vicinity of the plant. In response to the Gould (2000) report, comments received from the public, and the July 17, 2001, submittal from RPHP, the NRC staff conducted a careful examination of the issue. The staff reviewed effluent release reports, State of Florida environmental monitoring reports, and records of cancer incidence in south Florida. The staff also reviewed the open literature, discussed the claims of the RPHP with recognized experts in the field, and discussed the claims of elevated cancer incidence with State of Florida officials. The NRC staff continues to maintain that the current standards for radiation protection are adequate to protect public health and safety, that the Turkey Point Plant is not releasing strontium-90 in amounts that could be potentially dangerous to nearby residents, that there are no elevated levels of childhood cancer in the vicinity of Turkey Point

Plant, and that no causal link had been established between Turkey Point Plant operation, elevated levels of strontium-90 in the environment around the plant, and childhood cancer.

Summary of Comments

Following publication of the draft SEIS, there were additional comments, both written and at the public meeting, related to the subject of the work by Gould et al. and the RPHP comments (Mangano et al. 2001). The comments focused on five primary issues related to the discussion of the Gould study. The first issue was use of in-body measurement of radionuclides to determine public health effects. The second issue was use of strontium-90 to perform “in-body” measurement to evaluate the potential health risks from release of radioactive materials from Turkey Point Units 3 and 4. The third major issue described was increased cancer incidence in southern Florida, near Turkey Point Units 3 and 4. The fourth issue was the assertion that the BEIR V Report of the National Academy of Sciences’ committee on the Biological Effects of Ionizing Radiation (BEIR) concluded there is no safe exposure to radiation (National Resource Council 1990). Finally, a fifth major issue is the implication of a cause-and-effect relationship between reactor operation, catastrophic events and perceived increase in cancer rates.

The discussion that follows (1) explains the source and amount of strontium-90 in the environment; (2) describes the NRC’s basis for developing regulations related to protecting public health based on consensus standards by national and international organizations; (3) addresses the radiological monitoring programs at nuclear power reactors and specifically the program at Turkey Point Units 3 and 4; (4) explains why “in-body” measurement of radioactive materials is not used to determine public health impacts; (5) refutes the statements regarding cancer incidence discussed in the Gould report and public comment using a study performed by the Florida Department of Health; and (6) disputes the implication that radioactive effluents from nuclear reactors are the cause of perceived increases in cancer incidence near Turkey Point.

Strontium-90 in the Environment

There are three sources of strontium-90 in the environment: fallout from nuclear weapons testing, releases from the Chernobyl accident in Ukraine and releases from nuclear power reactors. By far the largest source of strontium-90 is from weapons testing fallout.

Both strontium-89 and strontium-90 were released to the atmosphere by above-ground explosions of nuclear weapons (United Nations Scientific Committee on the Effects of Atomic Radiation [UNSCEAR 2001]). Although the United States performed its last atmospheric test of a nuclear weapon in 1963, other countries continued to perform atmospheric testing of nuclear weapons until 1980 (UNSCEAR 2001). Strontium-89 has a half-life of 50.5 days, while the half-life of strontium-90 is 28.8 years. Consequently, virtually no strontium-89 currently remains in the soil from nuclear weapons testing (Eisenbud 1987). In contrast, strontium-90 remains in soils of the Northern Hemisphere at more than 50% of its peak levels in the 1960s (UNSCEAR 2000). Approximately 622 PBq (16.8 million Ci) of strontium-90 were produced and globally dispersed in atmospheric nuclear weapons testing.

Numerous measurements of the global disposition on strontium-90 and the occurrence of these and other fallout radionuclides in foodstuffs and the human body were made at the time the atmospheric tests were taking place. The worldwide average effective dose from ingesting

strontium-90 (1945 to date) is 97 μSv (9.7 mrem). The worldwide average effective dose from inhaling strontium-90 (1945 to 1985) is 9.2 μSv (0.92 mrem). No statistically significant excess of biological effects due to strontium-90 exposures at levels characteristic of worldwide fallout has been demonstrated (NCRP 1991).

The other two sources of strontium-90 in the environment are from the Chernobyl accident in April 1986 when approximately 8 PBq (216,000 Ci) of strontium-90 were released into the atmosphere, and strontium-90 released from nuclear power reactor operations. The total annual release of strontium-90 into the atmosphere from all U.S. nuclear power plants is typically 37 MBq (1/1,000th of a Ci). The amount of strontium-90 released into the environment from a nuclear facility is so low that the only chance of detecting strontium-90 is sampling the nuclear power plant effluents themselves. In addition to strontium-90, power reactors also release very small quantities of strontium-89.

Because of the extremely small amount of strontium-90 released from nuclear power plant effluents, it is unlikely that strontium-90 found in deciduous teeth would be from nuclear power plants. Without determining that there is strontium-89 in the teeth, it is impossible to tell where the strontium-90 is from. If there is no strontium-89 in the teeth, then it is unlikely that the strontium-90 is from a recent release from a nuclear reactor. The fact that the RPHP has failed to measure the strontium-89 to strontium-90 ratio in any deciduous teeth collected limits conclusions regarding the source of the internal contamination.

Regulatory Basis and Discussion of Risk

The evaluation of health effects from exposure to radiation, both natural and man-made, is an ongoing activity involving public, private, and international institutions. International and national organizations such as the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) provide consensus standards developed from recent and ongoing research. NRC's regulatory limits for effluent releases and subsequent dose to the public are based on the radiation protection recommendations of these organizations. NRC provides oversight of all licensed commercial nuclear reactors to ensure that regulatory limits for radiological effluent releases and the resulting dose to the public from these releases are within the established limits. The regulations related to radiological effluents and dose to the public can be found in 10 CFR Part 20 and 10 CFR Part 50, Appendix I.

The National Academy of Sciences' Committee on the BEIR published its fifth report (BEIR V) just over a decade ago (National Research Council 1990). That report contains mathematical models that predict risk of radiation-induced cancers in human populations over and above the incidence of cancer that occurs in the absence of radiation exposure. The BEIR V committee chose a linear, nonthreshold (LNT) dose-response model for solid cancers and a linear-quadratic (LQ) model for leukemia.

The BEIR V report does not address what is safe or not safe; it merely evaluates excess cancer risk in terms of probabilities. ICRP Publication 60 (1991), however, does define safe in the sense of "acceptable risk," and this and similar definitions are consistent with the NCRP (NCRP 1993) and the U.S. Environmental Protection Agency (EPA 1987). These implicit definitions of "safe" are embodied in all U.S. radiation protection regulations, including those of the NRC.

There is no human activity without some risk, however slight, so “safe” does not mean “with no risk,” but rather “safe” means “with an acceptably tiny risk.” What risk is acceptable from society’s standpoint is determined by the political process in the United States as spelled out recently, for example, by the U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management¹ (Omenn et al. 1997).

Effluent Monitoring at Turkey Point

Regulatory Guide 1.21 recommends that “a quarterly analysis for strontium-89 and strontium-90 should be made on a composite of all filters from each sampling location collected during the quarter.” The sensitivity is such that the analysis for radioactive material in particulate form should be sufficient to permit measurement of a small fraction of the activity, which would result in annual exposures of 0.15 mSv (15 mrem) to any organ of an individual, or 0.05 mSv (5 mrem) to the whole body, in an unrestricted area. Nuclear power plants, including Turkey Point Units 3 and 4, routinely release small amounts of radioactive material in their effluents. To demonstrate that the plant is within the regulatory limits, the plants monitor the radiological materials released to the environment and take frequent radiological samples around the plant site as well as analyze their effluent discharge. Both strontium-89 and strontium-90 can be found in power plant effluents in very small quantities. Each nuclear power plant in the United States is required to submit an annual report on effluent releases to NRC. The report contains information about the types and quantities of radionuclides that are released to the environment, as well as the dose impact on the environment.

Gaseous and liquid effluent releases are monitored at Turkey Point Units 3 and 4 to demonstrate that they are within regulatory limits. The licensee also has a Radiological Environmental Monitoring Program (REMP) that provides the procedures for monitoring releases to the environment. The results of this monitoring are provided to NRC in annual reports titled *Annual Radioactive Effluent Release Report* and *Annual Radiological Environmental Operating Report* (FPL 2000a and FPL 2000b). The effluent release program and the REMP for the Turkey Point plant were both reviewed. The releases of radionuclides to the environment, including strontium-90, are monitored as prescribed by FPL’s *Offsite Dose Calculation Manual* (FPL 1999) and have been maintained well below regulatory limits. During 2000, Turkey Point Units 3 and 4 did not release detectable levels of strontium-90 in the gaseous effluents. Liquid effluents containing radioactive materials, including strontium-90 and strontium-89 were released into the closed system cooling canals. The only time radioactive strontium was released in detectable levels in the liquid effluents was during the second quarter and the releases were 0.12 MBq (3.2 E-06 Ci) of strontium-90 and 0.37 MBq (10 E-06 Ci) of strontium-89 (FPL 2000b). To put this value in perspective, for the second quarter of 2000, the total amount of radioactive effluents released from Turkey Point Units 3 and 4 were about 150 times **below** NRC regulatory limits (.00663 percent of applicable limits). The quantity of gaseous and liquid materials released for 2000 are comparable to the quantities released in the past 5 years and the expected quantities released in years to come, including the license renewal period.

¹Telephone: (202) 233-9537, Fax: (202) 233-9540, Internet: <http://www.riskworld.com>

Use of “In-Body” Radionuclide Measurements to Assess Public Risk from Radiological Effluents from Turkey Point Units 3 and 4

Comments on the Turkey Point SEIS have stated or implied that the NRC should measure radioactive substances in persons living near nuclear power plants. Such measurements would be misleading and unwarranted for a variety of reasons:

- Radioactive substances may come from a variety of sources. In the case of strontium-90, the primary source has always been fallout from atmospheric weapons tests (UNSCEAR 2001). The comments on the SEIS that imply that strontium-90 measured in people near nuclear plants must have come from nuclear plants has no basis.
- Interpreting measurements of radioactive materials in people is difficult unless one knows what each individual was exposed to, when the exposures occurred, and by what routes they occurred (ingestion, inhalation, etc.). In particular for strontium-90, dietary contributions from foodstuffs produced out of the region must be considered. Finally, migration must be accounted for, because people may have lived and acquired radionuclides elsewhere than near a nuclear power plant.
- Substances in the human body are dynamic, not static. This includes radioactive and nonradioactive substances. The dynamic processes include intake of material; uptake to systemic circulation from the gastrointestinal tract, respiratory tract, or skin; translocation throughout the body system; retention over time; and elimination via excretion and radioactive decay. Thus, even in deciduous teeth, the time course of exposure leading to intake and all other dynamic processes must be considered to interpret measurements.

Increased Cancer Incidence in the Area of Turkey Point

Due to the concern from the issues regarding the increased cancer rates raised by RPHP, the Florida Department of Health chose to also look at the cancer rates using the same data used by RPHP. Staff from the Florida Bureau of Environmental Epidemiology interviewed the RPHP staff to determine the source of data and then performed their own calculations. They were unable to identify any unusually high rates of cancers, nor any systematic trend for some county rates to be higher than State or national levels. These rates fluctuate from year to year, and, in some situations, fluctuate widely due to a small number of cases in small populations (FDOH 2001).

Ability for Strontium-90 to Cause Cancer

Mangano et al., (2001), states that strontium-90 is “one of the most toxic radioactive chemical(s) produced by reactors.” Strontium-90 is produced in roughly 5.8% of nuclear fissions in a reactor’s fuel elements, and undergoes radioactive decay with a half-life of almost 29 years. Strontium-90, and its radioactive decay product yttrium-90, are not harmful unless they are near or inside the body. They are easily shielded if outside the body, resulting in no radiation exposure.

If ingested, strontium-90 tends to mimic calcium when it is in the body and therefore becomes concentrated in calcified tissues such as bones and teeth. If ingested in quantities that produce

very large radiological dose rates (about thousand times higher than dose rates we all receive from natural background [Raabe 1994]), strontium-90 is known to increase the risk of bone cancer and leukemia in animals, and is presumed to do so in people. Below these dose rates, there is no evidence of any excess cancer.

Compared to other radionuclides, both natural and human-made, strontium-90 is not the most toxic. For example, naturally occurring thorium-230 is 700 times more radiotoxic for inhalation.

Cause-and-Effect Relationship Between Radiological Releases from Turkey Point and Increased Incidence in Cancers in the Area

Comments on the Turkey Point SEIS have stated or implied that claimed statistical associations between cancer rates and reactor operations are cause-and-effect relationships. Many excellent scientific minds have addressed the question of when one can decide that an association is causal, that is, when two things that appear to be associated over time can lead one to deduce that one causes the other.

A simple counterexample helps illustrate this point. A college professor gives the following example of a causal inference: "In the winter I wear galoshes. In the winter I get colds. Therefore, galoshes cause colds." There's no argument that a strong statistical association exists between wearing galoshes and the health effect of colds. There is, however, an argument about whether galoshes *cause* colds. So, how does one go about addressing whether this association is really causation?

Here are some of the major factors to consider before inferring that a statistical association is a causal one (Hill 1965):

- (1) Strength: Is a large effect observed, e.g., 32-fold lung cancer increase in heavy smokers?
- (2) Consistency: Is the effect consistently observed across studies?
- (3) Specificity: Does the effect occur in specific persons, for particular sites and types of disease.
- (4) Temporality: Does exposure precede disease? Is there a suitable latent period between exposure and clinical symptoms?
- (5) Biological Gradient: Is there a dose-response curve in which increasing dose leads to increasing response?
- (6) Biological Plausibility: Is there a plausible biological mechanism for the observed association?
- (7) Coherence: Does the cause-and-effect inference seriously conflict with generally known facts of the natural history and biology of the disease?
- (8) Experiment: Does intervention reduce or prevent the association?

(9) Analogy: Do other, similar agents produce the effects?

Statistical association alone does not prove causation. The RPHP work fails to meet many of these criteria, even if the strontium-90 measurements were the result of the nuclear power plant operations. In particular, they fail to meet criteria 1, 2, 3, 4, and 6.

Epidemiology is the study of patterns of health and disease in human populations. In 1995 an international group of experts assembled to help determine how to use epidemiology studies for risk assessments. Their work has been published (Federal Focus Inc. 1996) and a non-copyrighted summary can be found on the internet at <http://www.pnl.gov/berc/epub/risk/index.html>.

A disease cluster is a group of cases of a disease that appear around the same time in a limited geographic or occupational area. A very readable, non-technical analysis of “the cancer-cluster myth” has been published in a popular magazine (Gawande 1999). Gawande explains why infectious disease clusters can and should spur immediate investigations and perhaps intervention by public health officials, and yet why non-infectious disease clusters rarely, if ever, are verified (see, for example, Neutra 1990 and Reynolds et al. 1996). For cancer, which has a significant latency between exposure and appearance of clinical symptoms, apparent clusters are very misleading because of migration and confounding sources of exposure.

Additional Discussion on Cancer

Information regarding the relationships between environmental exposure to radiation and cancer as stated in the Gould report were not substantiated. One form of cancer the Gould report linked to strontium-90 exposure is “the extremely rare form of childhood cancer known as rhabdomyosarcoma” (Gould et al. 2000). Rhabdomyosarcoma is not rare; indeed it is the most common soft tissue sarcoma in children (American Cancer Society [ACS] 2001a), and is the fifth most common form of pediatric cancer (St. Jude Children’s Research Hospital 2001). Furthermore, no association has been documented between the incidence of rhabdomyosarcoma and any environmental condition, including toxic substances, air or water pollution, or radiation exposure (ACS 2001a).

While the Gould report is correct with regard to the general increase in cancer incidence in the United States (Gould et al. 2000), this increase does not appear to be due to environmental causes other than cigarette smoking. The National Cancer Institute (NCI 2001) states that

“It is true that a person’s chance of developing cancer within his or her lifetime is almost twice as great today as it was half a century ago, which means that doctors are seeing more cases of cancer than they did in the past. However, this increase is caused largely by the facts that people are living longer and cancer is more prevalent in older people. When corrected for the increasing average age of the population, cancer rates in the United States have actually been stable or even falling slightly in the past several years. Much of the rise prior to that was due to cigarette smoking, a well established and avoidable cause of cancer.”

The ACS (ACS 2001b) acknowledges that a dramatic increase in prostate cancer was noted between 1989 and 1992, but notes that this increase was apparent rather than real. They

suggest that it was due to earlier diagnosis in men without any symptoms by increased use of prostate-specific antigen (PSA) blood test screening. They note that prostate cancer incidence rates have declined significantly since 1992 (ACS 2001b).

With regard to cancer clusters, especially breast cancer deaths, that are identified by the Gould report (Gould et al. 2000), detailed studies of this phenomenon have yet to substantiate relationships with environmental exposures, especially from nuclear power plants. Scientists from the NCI conducted and are conducting studies of breast cancer death clusters in the northeastern United States, the Washington D.C. area, and San Francisco. Primary factors driving the observed differences appear to be regional differences in age of mother at first birth and mammography screening (Sturgeon et al. 1995).

At the request of Congress, the NCI conducted a study of cancer mortality rates around 52 nuclear power plants, including the Turkey Point Plant, nine DOE facilities, and one former commercial fuel reprocessing facility. The study covered the period from 1950 to 1984, and evaluated the change in mortality rates before and during facility operations. The study (Jablon, Hrubec, and Boice 1991) concluded the following:

“From the evidence available, this study has found no suggestion that nuclear facilities may be linked causally with excess deaths from leukemia or from other cancers in populations living nearby.”

Additionally, the ACS (ACS 2001c) has concluded that although reports about cancer case clusters in such communities have raised public concern, studies show that clusters do not occur more often near nuclear plants than they do by chance elsewhere in the population. Likewise, there is no new evidence that links strontium-90 with increases in breast cancer, prostate cancer, or childhood cancer rates. The ACS recognizes that public concern about environmental cancer risks often focuses on risks for which no carcinogenicity has been proven or on situations where known carcinogen exposures are at such low levels that risks are negligible. “Ionizing radiation emissions from nuclear facilities are closely controlled and involve negligible levels of exposure for communities near such plants “ (ACS 2001c).

Conclusion

Doses to members of the public from Turkey Point Units 3 and 4 emissions were specifically evaluated in Section 4.6 of the GEIS, using data from monitored emissions and ambient monitoring, and were found to be well within regulatory limits.

The staff extensively reviewed the Gould report, comments received during scoping, information provided by the RPHP, comments from concerned citizens at the public meetings held in July 2001 at Homestead, Florida, and written comments submitted by interested citizens, the industry and other governmental agencies. The staff has concluded that the claims of elevated levels of childhood cancer in the vicinity of the plant caused by the release of strontium-90 during routine operations is unfounded and without scientific merit. According to an independent study by the State of Florida, there are no elevated levels of childhood cancer in the vicinity of the plant. Additionally, environmental monitoring by the State of Florida as well as in-plant monitoring of effluent streams has established that there are no significant releases of strontium-90 from the plant. No causal relationship has been established between the levels of strontium-90 being

reported by the RPHP in deciduous teeth and childhood cancer. Furthermore, U.S. current radiation protection standards are based on radiation protection recommendations of both international and national organizations.

References

- American Cancer Society (ACS). 2001a. "Rhabdomyosarcoma." Revised 1/18/2001. Accessed online: http://www3.cancer.org/cancerinfo/load_cont.asp?ct=53&language=English.
- American Cancer Society (ACS). 2001b. "Prostate Cancer." Accessed online: <http://www3.cancer.org/cancerinfo/sitecenter.asp?ct=1&ctid=8&scp=8.3.2.40030&scs=4&scss=10&scdoc=42009&pnt=2&language=english>.
- American Cancer Society (ACS). 2001c. "1998 Facts & Figures. Environmental Cancer Risks." Accessed online: <http://www.cancer.org/statistics/cff98/enviromental.html>.
- Eisenbud, M. 1987. *Environmental Radioactivity, 3rd Edition*. Academic Press, San Diego, California.
- Federal Focus Inc. 1996. *Principles for Evaluating Epidemiologic Data in Regulatory Risk Assessment*. Developed by an Expert Panel at a Conference in Long, England, October 1995. Available at <http://www.pnl.gov/berc/epub/risk/index.html>. Federal Focus, Inc., Washington, D.C.
- Florida Department of Health (FDOH). 2001. *Report Concerning Cancer Rate in Southeastern Florida*. Bureau of Environmental Epidemiology, Division of Environmental Health, Tallahassee, Florida.
- Florida Power & Light Company (FPL). 1999. *Offsite Dose Calculation Manual for Gaseous and Liquid Effluents from the Turkey Point Plant Units 3 and 4*. Revision 8, Miami, Florida.
- Florida Power & Light Company (FPL). 2000a. *Turkey Point Plant Units 3 and 4 Annual Radioactive Effluent Release Report, January 1999 through December 1999*. Miami, Florida.
- Florida Power & Light Company (FPL). 2000b. *Florida Power & Light Turkey Point Units 3 & 4 1999 Annual Radiological Environmental Operating Report*. Miami, Florida.
- Florida Power & Light Company (FPL). 2001. *Turkey Point Units 3 and 4 Annual Radioactive Effluent Release Report, January 2000 through December 2000*. Miami, Florida.
- Gould, J. M., E. J. Sternglass, J. D. Sherman, J. Brown, W. McDonnell, and J. J. Mangano. 2000. "Strontium-90 in deciduous teeth as a factor in early childhood cancer." *International Journal of Health Services*. Vol. 30, No. 3.
- Gawande, A. 1999. "The Cancer-Cluster Myth." *The New Yorker* LXXIV(45):34-37.
- Hill A. B. 1965. "The Environment and Disease: Association or Causation?" *Proceedings of the Royal Society of Medicine* 58:295-300.

International Commission on Radiological Protection (ICRP). 1991. "1990 Recommendations of the International Commission on Radiological Protection." (ICRP Publication No. 60) *Annals of the ICRP* 21(1-3), Pergamon Press, New York.

Jablon, S., Z. Hrubec, and J. D. Boice, Jr. 1991. "Cancer in populations living near nuclear facilities, A survey of mortality nationwide and incidence in two states." *Journal of the American Medical Association*. 265:1403-1408.

Mangano, Joseph, et. al. 2001. *Comment on Draft Report and Submission of New Information, Generic Environmental Impact Statement, Supplement 5 Regarding Florida Power and Light Company's Proposal to the U.S. Nuclear Regulatory Commission to Re-license the Turkey Point 3 and 4 Reactors (NUREG-1437, Supplement 5)*, Radiation and Public Health Project. New York.

National Cancer Institute (NCI). 1990. *Cancer in Populations Living Near Nuclear Facilities*. Bethesda, Maryland.

National Cancer Institute (NCI). 2001. "Is there a cancer "epidemic?" Accessed online: <http://rex.nci.nih.gov/behindthenews/uc/ucframe.html>.

National Council on Radiation Protection and Measurements (NCRP). 1991. *Some Aspects of Strontium Radiobiology*. Report No. 110, NCRP Publications, Bethesda, Maryland.

National Council on Radiation Protection and Measurements (NCRP). 1993. *Limitation of Exposure to Ionizing Radiation*. Report No. 116, NCRP Publications, Bethesda, Maryland.

National Research Council. 1990. *Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V)*. National Academy Press, Washington, D.C.

Neutra, R. R. 1990. "Counterpoint from a cluster buster." *Am. J. Epidemiol.* **132**(1):1-8.

Omenn, G. S., A. C. Kessler, N. T. Anderson, P. Y. Chiu, J. Doull, B. Goldstein, J. Lederberg, S. McGuire, D. Rall, and VV. Weldon. 1997. *Framework for Environmental Health Risk Management. Final Report. Vol. 1*. U.S. Government Printing Office, Washington, D.C.

Raabe, O. G. 1994. "Three-Dimensional Models of Risk From Internally Deposited Radionuclides." Chapter 30 in *Internal Radiation Dosimetry*, ed. O. G. Raabe, pp. 633-658. Medical Physics Publishing, Madison, Wisconsin.

Reynolds, P., D. F. Smith, E. Satariano, D. O. Nelson, L. R. Goldman, and R. R. Neutra. 1996. "The four county study of childhood cancer: clusters in context." *Statistics in Medicine* **15**(7-9):683-697.

St. Jude Children's Research Hospital. 2001. "Rhabdomyosarcoma." Accessed online: <http://www.stjude.org/medical/rhabdomyosar.htm>.

Sturgeon, S. R., C. Schairer, M. Gail, M. McAdams, L. A. Brinton, and R. N. Hoover. 1995. "Geographic Variation in Mortality from Breast Cancer Among White Women in the United States." *Journal of the National Cancer Institute*. 87:1846-1853.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). 2000. *Sources and Effects of Ionizing Radiation, Vol. 1: Sources*. United Nations, New York.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). 2001. *Sources and Effects of Ionizing Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes. Vol. I: Sources*. United Nations, New York.

U.S. Environmental Protection Agency (EPA). 1987. "Radiation Protection Guidance to Federal Agencies for Occupational Exposure." *Federal Register* **52**(17):2822-2834.

U.S. Nuclear Regulatory Commission (NRC). 2001. *Draft Supplement 5 to the Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Turkey Point Units 3 and 4*. NUREG-1437, May 2001, Washington, D.C.