Attachment F

Letter from Dr. Ricky Langley, NC Dept. of Health and Human Services providing response to request for evaluation of risk from thermophilic organisms dated June 12, 2000

North Carolina
Department of Health and Human Services
Division of Public Health
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Ann F. Wolfe, M.D., M.P.H., Director

June 12, 2000

Ms. Mary Santini
Group Environmental Health & Safety
Duke Power Company
1339 Hagers Ferry Road (MG03A3)
Huntersville, North Carolina 28078-7929

Dear Ms. Santini:

Enclosed are examples of theoretical risk assessments for *Naegleria fowleri* from different areas of the United States and utilizing different methodologies. Since the presence or absence of N. fowleri in Lake Norman is not known, a site-specific risk assessment is not possible at this time. As noted in a letter to Dr. Steve Cline on February 16, 2000, the US Nuclear Regulatory Commission (NRC) requires that an applicant assess certain site-specific environmental issues including the impact of thermophylic organisms (*Naegleria fowleri)* on public health. The USNRC suggest that the applicant consult with state agencies as to whether there is a concern about the potential existence and concentration of *Naegleria fowleri* in the receiving waters for the plant cooling water discharge.

Based on discussions with the Centers for Disease Control and Prevention (CDC) that only a small percentage of cases of amebic meningoencephalitis have been associated with thermally enhanced waters, the rarity of the disease given the millions of swimming events in warm fresh water bodies in the United States, the low theoretical risk as shown in the attached report, and the lack of "action levels", the North Carolina Department of Health and Human Services (NCDHHS) feels the risk to individuals utilizing Lake Norman for recreational activities is extremely low. Sampling is not recommended by the NCDHHS at this time for Naegleria. In the future, if a regulatory agency requires a site-specific risk assessment, then the actual concentration of this organism in Lake Norman would need to be determined in order to do a risk assessment for Lake Norman. Additionally, an updated estimate of the number of individuals using Lake Norman for recreational purposes (swimming, diving, and skiing) should be determined so a risk estimate based on the exposed population can be calculated. If sampling is undertaken, the Centers for Disease Control and Prevention recommend sampling for *Naegleria fowleri* 3-4 times during the first summer. If no organisms are found, then sampling 1-2 times a summer for the next two years would be recommended.

If Duke Power Company decides on sampling based upon requirements or recommendations from other agencies, the North Carolina Division of Public Health would be glad to assist you in performing an actual risk assessment for Lake Norman once the sampling and population estimates are completed. However, if there is a case of amebic meningoencephalitis associated with Lake Norman, the NCDHHS Division of Public Health would conduct an investigation, and at that time, determine if sampling for this organism would be indicated to protect the public's health. If you have additional questions, please contact me at (919) 715-6428.

Sincerely,

Ricky Langley, MD, MPH
Medical Evaluation and Risk Assessment Unit
Occupational and Environmental Epidemiology Branch

RL:mbf

Attachment

c: Dr. Steve Cline, DDS MPH
Dr. Bill Tynan, MD MPH
Bill Pate, MSPH, CIH
Dr. Newt McCormack, MD MPH

Theoretical Risk Assessment of *Naegleria fowleri* Induced Meningoencephalitis Utilizing Various Methodologies

Duke Power Company has asked the North Carolina Department of Health and Human Services to comment on the public health concerns regarding the potential presence of *Naegleria fowleri* and other thermophilic organisms in the portion of Lake Norman affected by McGuire nuclear plant's discharge canal. As part of a renewal of its operating license, the US Nuclear Regulatory Commission requires that an applicant (Duke Power in this case) assess certain site-specific environmental issues related to the continuing operation of the plant. As part of this evaluation, the NRC suggest that an applicant consult with state agencies responsible for environmental health as to whether there is a concern about the potential existence of *N. fowleri* in the receiving waters for the plant's cooling water discharge. (1)

The McGuire Nuclear Station Unit 1 became operational in 1981 and Unit 2 became operational in 1984. The McGuire nuclear plant uses Lake Norman as a source for condenser cooling water. The heated effluent from the condenser discharge enters Lake Norman through a discharge canal. The canal is 0.6 miles long with an average depth of 40 feet. The heated effluent mixes initially in the canal with surface waters of the lake before the temperature stabilizes. The average monthly discharge water temperature ranged from 67.0 degree F in February to 97.4 degree F in August 1997. Swimming and boating are not allowed in the canal, although fishing is permitted from its banks. Boating, fishing, and water contact takes place at the confluence of the canal and the lake. The closest privately owned dock is <0.25 miles away. (1)

There are several microorganisms, many pathogenic to humans, whose presence may be enhanced by thermal additions to natural water bodies. Among these are *Salmonella* species, *Aeromonas* species, *Shigella* species, *Pseudomonas* species, thermophilic fungi, *Legionella* species and the free living *Naegleria* species. (2) Pathogenic *Naegleria* have been isolated from discharge waters of nuclear power plant cooling reservoirs. (3) According to Dr. G. S. Visvesvara of the Centers for Disease Control and Prevention (CDC) (personal communication, May 18, 2000), approximately 3-5% of the cases of amebic meningoencephalitis has been associated with thermally enhanced waters.

According to information provided by Mary Santini, microbiologist with Duke Power Company (personal communication, April 2000), numerous data on water quality including dissolved oxygen (DO), water chemistry, phytoplankton, zooplankton, and fisheries monitoring are collected yearly on Lake Norman. However, while coliforms are being monitored for, *Naegleria* sp. are not monitored for in the discharge canal. Because the presence of *Naegleria fowleri* is unknown, a site-specific risk assessment is not possible. However, different methodologies have been utilized to try to derive a theoretical risk and these are discussed below.

Infection of humans with free-living ameba is infrequent, but can be a life-threatening event in both healthy and immunocompromised individuals. Examples of free-living amebic species include *Naegleria*, *Acanthamoeba*, and *Balamuthia*. Free-living ameba can cause three distinct clinical syndromes: primary meningoencephalitis, granulomatous amebic encephalitis, and amebic keratitis. (4) *N. fowleri* is predominantly associated with primary amebic meningoencephalitis.

Naegleria fowleri, also known as *N. aerobia* or *N. invadens*, is the only recognized pathogenic species of Naegleria. *N. fowleri* is thermophilic with the trophozoite form growing well at temperatures as high as 113 degrees F. The presence of *N. fowleri* in fresh water is directly related to water temperature. As the water temperature drops during the winter, Naegleria trophozoites form cysts that can be isolated from lake bottom sediments.

Primary amebic meningoencephalitis occurs primarily in healthy children and young adults who have recently swam in warm freshwater lakes or ponds. The ameba penetrates the nasal submucosal nervous plexus and the cribriform plate and gain access to the central nervous system. *N. fowleri* produces

a diffuse meningoencephalitis and purulent leptomeningitis with severest involvement of the cortical gray matter. A diffuse or focal myocarditis is often seen in patients with primary meningoencephalitis. (4) Unfortunately, the case mortality rate is over 90% in patients with primary meningoencephalitis.

By immunologic testing, it appears that the majority of young adults, but not infants, have been exposed to *N. fowleri*. Healthy children and young adults are the chief victims of *N. fowleri* infection. The factors that protect most individuals from invasive disease are not known. As of 1997, approximately 179 cases of primary meningoencephalitis have been reported worldwide with 81 cases in the United States. In North Carolina three cases have been reported with none attributed to Lake Norman as the water source. Two were from the same lake and none were associated with thermally enhanced water discharges.

Studies have been done on the risk of developing meningoencephalitis from contact with fresh water. Wellings and colleagues have estimated that there have been a billion exposures of people to Naegleria contaminated fresh waters with only seven cases reported in Florida in a 14 -year period of time. (5) This calculates to a risk of 1 case per 142,857,140 exposures over 14 years or 0.007 cases per million exposures or an annual occurence of 0.5 cases per year in Florida.

One other risk assessment by Martinez (6) is based on an average of two cases per year in the US (1965-1991) and an estimated 60,277,000 swimming exposures (fresh and salt water) annually providing an estimate of 0.033 cases per million persons exposed to recreational waters. Since it was not possible to differentiate salt and fresh water contact, the actual risk from freshwater contact would be higher.

By comparison, Hallenbeck and Brenniman (7) developed a risk estimate for estimating the number of cases and individual risks resulting from primary freshwater contact based on seven cases of primary amebic meningoencephalitis over 14 year exposure period in Florida.

Equation 1: CASES (annual) = $3.8 \times 10^{-7} \times N$ N is the number of exposures at a lake during a swimming season and 3.8×10^{-7} is the Welling's risk factor (cases per exposure)

The total number of cases over some period of time can be calculated as follows

Equation 2: CASES (total) = $3.8 \times 10^{-7} \times N \times S$ S is the number of swimming seasons

Equation 3: Individual risks (annual) = $3.8 \times 10^{-7} \times E$ E is the number of swimming exposures per person per season

The total individual risk over some period of time can be calculated as

Equation 4: Individual risk (total) = $3.8 \times 10^{-7} \times E \times S$

Assuming the mixture of exposure types (swimming. skiing, diving) are the same as in Florida lakes and that the lake ecology is similar to lakes in Florida, a risk estimate using the formulas above can be calculated.

A third risk assessment method has been developed that has used an animal model and extrapolated the risk to humans. (9) Mice were exposed by swimming for five minutes in water seeded with known concentrations of *N. fowleri* in order to establish a dose-response relationship. When actual reported concentrations of *N. fowleri* were used to predict risk to humans using a linear two population model, the risk to humans for a five-minute exposure ranged from 0.0132 cases per billion exposures for 1 pathogenic ameba per 560 liters in thermally polluted and freshwater lakes in Florida, to 2.7 cases per billion exposures 1 pathogenic ameba per 3.4 liters in a fresh water body in Oklahoma, up to 1.48 cases per million exposures when the highest measured concentration of 1 pathogenic ameba per 5 milliliters water

collected from a man-made artificial cooling lake in South Carolina. The concentrations of pathogens used in the table represent concentrations of pathogenic Naegleria found in environmental waters at three different sites in the United States.

TABLE 1. Concentrations of Pathogenic Ameba in Environmental Waters

SITE	CONCENTRATION OF AMEBA	CALCULATED HUMAN RISK
South Carolina	1 Pathogen / 5 Milliliters	1.48 cases per million exposures
Oklahoma	1 Pathogen / 3.4 Liters	2.17 cases per billion exposures
Florida	1 Pathogen / 560 Liters	0.0132 cases per billion exposures

Using these three different risk assessments models, the theoretical risk of human meningoencephalitis due to *N. fowleri* occurring would range from 0.007 cases per million exposures (based on Florida exposure data over a 14-year period of time) to 1.48 cases per million exposures (based on extrapolation from mice to humans data and a calculated human risk from a South Carolina thermal input water). Sources of uncertainty in the risk assessments include the concentration of pathogenic amebas in the environment, fraction of the population swimming in the waters, length of swim, relative fraction of amebas that reach the brain after entering the nasal passages in mice and humans, and the immune reaction efficacy in mice and humans. (9)

In contrast, drownings are much more frequent occurrences in North Carolina. Accidental drownings in N.C. for 1994-1998 are shown below: (North Carolina Medical Examiners Office)

Year	Number of drownings
1998	98
1997	88
1996	104
1995	111
1994	97

Based on a 1995 population estimate of 7,186,050 in N.C. and the average number of yearly drownings of 99.6 for 1994-1998, then the risk of drowning is 13.86 per million persons. The North Carolina Division of Parks and Recreation estimated from a 1995 survey that there are an annual average of 19,069,390 swimming exposures in rivers, lakes, and the Atlantic Ocean and 23,173,846 swimming exposures in pools in North Carolina. Based on the total number of exposures, the risk of drowning from all swimming exposures is 2.35 per million swimming exposures.

In conclusion, because it is not known if *Naegleria fowleri* is present in Lake Norman as no one monitors for this organism there, no cases of amebic meningoencephalitis have been reported from Lake Norman, and the theoretical risk of developing amebic meningoencephalitis is extremely low from swimming in Lake Norman, the Department of Health and Human Services does not recommend posting Lake Norman for Naegleria at this time. To do a site-specific risk assessment, then the actual concentration of pathogenic Naegleria in Lake Norman, especially around the thermal discharge canal, would have to be determined on an ongoing basis. The CDC recommends sampling three to four times the first summer. If no Naegleria are found initially, then repeat sampling one to two times the next two summers (personal communication with Dr. Visvesvara, CDC). Additionally, more updated information on the number of visitors to Lake Norman recreational waters is needed. Once the actual concentration of pathogenic ameba is determined, then an actual risk assessment for this body of water can be calculated. In the future, if a case of amebic meningoencephalitis is reported from Lake Norman, the issue of posting will need to be reexamined.

REFERENCES

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3. Huizinga H, McLaughlin G. Thermal ecology of Naegleria fowelri from a power plant cooling reservoir. Applied and Environmental Microbiology, 1990, Vol. 56, p. 2200- 05.

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5. Wellings F. Amoebic meningoencephalitis. Journal of the Florida Medical Association. 1977, Vol. 64, p. 327-8.

6. Martinez A. Free-living ameba: infection of the central nervous system. The Mount Sinai Journal of Medicine. 1993, Vol. 60, p. 271-8

7. Hallenbeck W, Brenniman G. Risk of fatal meningoencephalitis from waterborne Naegleria fowleri. Environmental Management, 1989, Vol. 13, p. 227-32.

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9. Davis A. E. Naegleria fowleri: Assessing the Risk from a Free-Living Ameba. Master's Technical Report, University of North Carolina-Chapel Hill. 1997.