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January 28, 2000

The Commissioners
U.S. Nuclear Regulatory Commission
Washington, DC 20555

SERVED FEB - 9 2000

The Hon. Peter B. Bloch, Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852

To the Commissioners and Judge Bloch:

As a family practice physician now working at the Crownpoint Healthcare Facility (CHF) in Crownpoint, N.M., I am writing to request that the license issued to Hydro Resources, Inc. (HRI), for the Crownpoint Uranium Project (CUP) be suspended immediately. The Nuclear Regulatory Commission's groundwater restoration standard for uranium of 0.44 milligrams per liter (mg/L) poses a significant threat to the health of the public. This standard is very likely to cause irreparable harm to the current and future residents of Crownpoint and the surrounding communities who drink water from the Crownpoint municipal water supply.

The research studies that the NRC used as a scientific basis for the groundwater restoration standard of 0.44 mg/L are outdated and flawed. More contemporary studies, which are of higher quality and are more generalizable to human populations, demonstrate that humans show signs of kidney damage after consuming water with levels of uranium a slow as 0.014 mg/L. The NRC unfortunately has overlooked these relevant studies, which document important *subclinical* effects that can lead to later kidney disease and failure. I request, therefore, that the project be halted and the groundwater restoration standard be amended so that the standard requires HRI to return the uranium concentration in the restored water back to baseline levels.

I have reached these conclusions after reviewing your environmental impact statement for the project (NUREG-1508, dated February 1997), speaking at length on two occasions with a Nuclear Regulatory Commission radiation scientist who has worked on the HRI project, and having reviewed the current and historic literature on uranium's well-documented chemical toxicity. I believe I am qualified to give

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you my opinion on this important matter. I have been a medical doctor since 1993, I have worked for the New Mexico Department of Health on epidemiological issues involving preventive medicine, and I expect to complete a master's degree in public health at the University of New Mexico in 2001. In my MPH course work, I have taken several classes in epidemiology and environmental health. I am well versed in reviewing, understanding and interpreting the biomedical literature.

I had no detailed knowledge about the HRI project until I took a position as a family practice physician at the Crownpoint Hospital in August 1999. Soon after arriving here, I became aware of HRI's proposed solution mines because they are a matter of extensive local public discussion. As a physician, I have an obligation to ensure the health and wellness of my patients, so I was naturally concerned about any activity that could affect the integrity of the local water supply. Since then, as described below, I conducted my own research on this matter. I now feel prepared to share the results of my inquiry with you.

First, I obtained a copy of the *Final Environmental Impact Statement* (FEIS) and learned that NRC's "secondary restoration goal" for residual uranium levels in the aquifer after mining is 60 to 440 times greater than the background uranium concentrations in the town of Crownpoint's well waters.[1] The NRC's proposed uranium standard seemed quite high compared to the native water quality, so I began compiling and reading literature about the *chemical toxicity* of uranium. Two recent studies documenting toxic effects of chronic uranium ingestion on kidney functions are notable. I review and explain their importance later in this letter.

Second, I spoke by telephone with Mr. Christepher McKenney, an NRC staff radiation scientist, on December 29 and December 30, 1999. He sent me a copy of an affidavit he had prepared in February 1998.[2] On page 6 of his affidavit, Mr. McKenney wrote that in his opinion, "the secondary groundwater restoration goal for uranium of 0.44 mg/L (300 pCi/L) is protective of public health and safety with respect to chemical toxicity to the kidneys." I asked him how the NRC had reached the conclusion that a restoration standard of 0.44 mg/L would be safe for human consumption. He stated that there is not much information regarding the chemical toxicity of uranium in water. He also stated that he had used research studies listed on the Integrated Risk Information System (IRIS) provided by the Environmental Protection Agency to reach the conclusion that 0.44 mg/L of uranium is safe.

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[1]This ranged is based on a comparison of the restoration standard, 0.44 mg/L, with the range of concentrations of uranium (0.001 to 0.007 mg/L) in the town wells reported Table 3.12 of the FEIS.

[2]Affidavit of Christepher A. McKenney, United States Nuclear Regulatory Commission, in the matter of Hydro Resources, Inc., Docket No. 40-8968-ML, February 20, 1998.

Mr. McKenney stated in his affidavit that ingestion of drinking water with 0.44 mg/L of uranium is protective of public health because it is below the ingestion standard of 10 mg/week of soluble uranium set by the NRC. He further stated that ingestion of 6.2 mg of uranium per week is "well below the exposure level at which renal failure would reasonably be expected to occur."

I obtained and reviewed the studies that Mr. McKenney cited to support the opinions he expressed to me and in his affidavit. I found that each of these studies, which were performed between 1949 and 1973, are methodologically flawed, poorly generalizable to human populations exposed to chronic ingestion of uranium, and outdated in light of more modern studies. Here follows my critique of each of those studies:

Maynard and Hodge, 1949.[3] This study involved animals including rats, dogs, and rabbits and had an exposure time of 30 days. The outcome measure of renal disease used in this study was based on histological examination of renal tissue. This method of examination is insensitive and provides evidence of anatomical damage and not functional damage, meaning the kidney could look normal but not work. The researchers did not look at markers for functional toxicity such as microalbumin or urinary enzymes. Furthermore the study used animals only exposed to short duration of uranium ingestion. It is next to impossible to reach conclusions about safe thresholds of uranium ingestion in human populations using this study.

Hursh et.al., 1969.[4] This study involved four hospital patients exposed to a single oral dose of uranium. The outcome measure chosen was urinary protein. The validity of this study is questionable because of the extremely small number of subjects and the insensitive outcome measure. The generalizability of the results to humans exposed to chronic ingestion of uranium is also questionable because of the single dose exposure and the use of hospitalized patients.

Hursh and Spoor, 1973.[5] This study looked at seven subjects who were exposed to a single injection of intravenous uranium. The study's outcome measures included urinary catalase, nitrogen, and glomerular filtration rate. Again the validity of this study is poor as it involved a small number of subjects and employed insensitive markers of renal damage. The generalizability of the study is certainly poor, as these were patients that received intravenous and not oral doses of uranium.

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[3] Maynard, EA and HC Hodge. 1949. Studies of the toxicity of various uranium compounds when fed to experimental animals. In: The Pharmacology and Toxicology of Uranium Compounds. Nations Nuclear Energy Service. Division VI, Vol. I, C. Voegtlin and HC Hodge, Eds. McGraw Hill, New York, NY. p 309-376.

[4] Hursh JB, WR Neuman, et.al. 1969. Oral ingestion of uranium by man. *Health Physics*. 17:619-621.

[5] Hursh, JB and NL Spoor. 1973. Data on Man. In: Uranium, Plutonium, Transplutonium Elements. HC Hodge, JN Stannard and JB Hursh, Ed. Springer-Verlag, Berlin. P197-239.

Novikov and Yadina, 1970.[6] This study looked at female rabbits exposed to oral doses of uranium for 12 months. The outcome measures were serum urea, creatinine clearance, and enzyme levels in tissue. This study has poor validity and is not generalizable as it involves animals and uses insensitive markers of disease.

Conventional biomedical science uses animal studies as the basis upon which to develop hypotheses in human populations. After animal experiments have been completed, human studies are conducted to prove or disprove those hypotheses. The NRC has used primarily animal studies and very small human experiments involving high doses given over very short periods of time to create the basis for the restoration standard. All of these studies contained several implicit assumptions that should be questioned in light of newer findings, namely that:

(1) there is no difference between acute and chronic exposure to uranium;
(2) humans and animals respond similarly when exposed to uranium;
(3) valid and sensitive biomarkers for disease were used.

These assumptions are likely to be incorrect. Studies undertaken in the early-to-mid 1990s and reported in 1995 and 1998 by researchers with the Laboratory Centre for Disease Control and the Department of Health in Ottawa, Canada were performed on healthy human populations exposed by ingestion, over long periods of time, to low levels of uranium. These newer studies employed more sensitive and sophisticated markers of kidney dysfunction and kidney cellular damage. The following is a brief description of these Canadian studies:

Mao Y. et. al., 1995.[7] This study compared people (100 subjects) who had been exposed to varying concentrations of naturally occurring uranium in their drinking water. These researchers found a statistically significant association between increasing uranium exposure in water and levels of microalbumin in the urine. Subjects who drank water containing levels of uranium as low as 0.014 mg/L (or 31 times *lower* than the NRC restoration standard) were found to have higher levels of microalbumin in their urine. Microalbuminuria, or the condition of having small amounts of protein in one's urine, is a known risk factor for stroke, heart attack, and kidney failure.[8] In other words, it is evidence of biological damage *before* disease symptoms are evident in the individual. We in the medical profession refer to these effects as the *subclinical stage* of the spectrum of disease.

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[6] Novikov, YV and TV Yudina. 1970. Data on the biological effect of small amounts of natural uranium in water. *Hyg. Sanit.* 35:225-216.

[7] Mao Y, Desmeules M, et. al. 1995. Inorganic Components of Drinking Water and Microalbuminuria. *Environmental Research.* 71:135-140.

[8] Luft FC. 1997. Microalbuminuria and essential hypertension: renal and cardiovascular implications. *Current Opinion in Nephrology and Hypertension.* 6(6):553-557.

Zamora ML et. al., 1998.[9] This study also looked at people (50 subjects) exposed to varying concentrations of uranium in their drinking water. The researchers used sensitive indicators of kidney function such as urinary proteins and enzymes as markers of injury. The study found an association between increasing uranium exposure and the presence of elevated levels of certain renal biomarkers that are indicative of injury to the kidney. This association was observed at uranium levels ranging from 3 ug/L to 570 ug/L; no association was observed at concentrations less than 1 ug/L.

The Mao and Zamora studies are important in several ways. First they were performed on human populations who had ingested uranium chronically in their drinking water and thereby create results that are more appropriate when generating standards for drinking water. Second, they found signs of renal injury at concentrations of uranium far below the restoration standard of 0.44 mg/L. And third, and most important, they employed more sensitive markers of injury which allowed the researchers to detect signs of disease at earlier stages than the studies from earlier years.

In my view, the consistency between the Mao and Zamora studies in demonstrating subclinical effects of uranium ingestion calls into question Mr. McKenney's notion, as expressed clearly in this February 1998 affidavit, that a level of uranium in drinking water is "safe" if it doesn't cause "renal failure." The public should not have to *develop severe disease* before regulatory agencies take action, through standards setting, to protect public health. But this is what the NRC appears to have done in the HRI case.

The NRC either overlooked or ignored these studies and relied instead on outdated and methodologically flawed research from years previous. In its decision to use 0.44 mg/L as a restoration standard, the NRC also ignored research and analysis used by the U.S. Environmental Protection Agency (USEPA) when it proposed a uranium drinking water standard of 0.020 mg/L in 1991. Several years before that, in 1983, Richard Cothern with USEPA's Office of Drinking Water concluded "it is deemed prudent to consider setting the health effects guidance level for uranium in drinking water at 10 pCi/L based primarily on health considerations."[10]

The Navajo people that I serve in Crownpoint already suffer from inordinate amounts of renal disease stemming from diabetes. Exposing this population to another known nephrotoxin is inviting disaster. Contemporary studies, ignored by the NRC, show that the restoration goal for uranium of 0.44 mg/L is not protective of public health and safety and is tantamount to malpractice.

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[9] Zamora ML, BL Tracy, et.al. 1998. Chronic Ingestion of Uranium in Drinking Water: A Study of Kidney Bioeffects in Humans. *Toxicological Sciences*. 43:68-77.

[10] Cothern CR, WL Lappenbusch, JA Cotruvo. 1983. Health Effects Guidance for Uranium in Drinking Water. *Health Physics*. 44:377-384.

As a physician concerned for the health and safety of the people of Crownpoint I ask that the license for the Crownpoint Uranium Project be amended so that the only acceptable restoration goal be to return the levels of uranium in the water back to baseline.

Respectfully,

John D. Fogarty, M.D.

THE FOLLOWING TWO ATTACHMENTS (COPYRIGHT) ARE RETAINED IN SECY/RAS:

1) CHRONIC INGESTION OF URANIUM IN DRINKING WATER: A STUDY OF KIDNEY BIOEFFECTS IN HUMANS

2) INORGANIC COMPONENTS OF DRINKING WATER AND MICROALBUMINURIA

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

HYDRO RESOURCES, INC.

Docket No.(s) 40-8968-ML

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LTR FOGARTY TO COMM & LB have been served upon the following persons by U.S. mail, first class, except as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

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Docket No.(s)40-8968-ML
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Dated at Rockville, Md. this
9 day of February 2000

Adria T. Byrdsong
Office of the Secretary of the Commission