RAS 7390

February 2, 2004

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
BEFORE THE SECRETARY

DOCKETED
USNRC

February 2, 2004 (2:00PM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

In the matter of	)	
	)	
Nuclear Fuel Services, Inc.	)	Docket No. 70-143
	)	
(Materials License SNM-124)	)	
	)	

THIRD REQUEST FOR HEARING
BY KATHY HELMS-HUGHES REGARDING NUCLEAR FUEL SERVICES'
PROPOSED BLENDED LOW-ENRICHED URANIUM PROJECT

I. INTRODUCTION

Petitioner Kathy Helms-Hughes hereby requests a hearing in the matter of Nuclear Fuel Service's (NFS's) filing of a third license amendment request for the Blended Low-Enriched Uranium (BLEU) Project at the NFS plant in Erwin, Tenn. Petitioner requests this hearing in accordance with the Nuclear Regulatory Commission's (NRC's) Notice of Receipt of Amendment Request and Opportunity to Request a Hearing for Oxide Conversion Building and Effluent Processing Building in the Blended Low-Enrichment Uranium Complex, 68 Fed. Reg. 74,653 (Dec. 24, 2003).

On Jan. 16, 2004, NRC Secretary of the Commission Annette L. Vietti-Cook granted Kathy Helms-Hughes (Petitioner) a 10-day extension of time to file a hearing request regarding NFS's third license amendment application. The time for filing a hearing request was extended until Monday, Feb. 2, 2004, after the NRC found the extension appropriate to account for end-of-the-year holidays. The notice of opportunity for a hearing on NFS's third license amendment application was posted in the Federal Register on Dec. 24, 2003.

Petitioner renews her request that any aspect of this hearing that is held as a public meeting be conducted locally, in the evening, so that working people can attend. Petitioner also renews her request for a site-specific Environmental Impact Statement to adequately assess impacts to public health, safety, and the environment.

II. STANDING

Helms-Hughes relies on and hereby incorporates by reference, discussion of standing, information and arguments contained in her declaration filed Nov. 29, 2002; her Jan. 6, 2003, Response to NFS's Motion to Deny Helms-Hughes Request for Standing and Leave to Intervene; her Jan. 26, 2003, Response to Applicant's Motion to Strike; her Feb. 6, 2003, Request for Hearing and Leave to Intervene; her March 7, 2003, reply to NFS's Response to Her Second Hearing Request.

Helms-Hughes owns three parcels of land in Butler, Tenn., her primary place of residence, less than 20 miles downwind of NFS, inside NFS's Region of Concern. The prevailing wind disperses airborne effluent in a northeasterly direction from NFS, right across Helms-Hughes' property and sole source of drinking water. That effluent consists of uranium, plutonium, americium and/or thorium which has been sent up the stacks at NFS since production began in 1957. The BLEU Project will result in increased emissions of uranium and thorium, according to the June 2002 Environmental Assessment.

Helms-Hughes, as well as caretakers of the property in her absence, farm the family's ancestral lands and drink spring water that flows across the property from the Cherokee National Forest. Additional airborne effluent dispersion by NFS will have a negative impact on their health and will place future generations at risk from the consumption and bioaccumulation of radioactive contaminants deposited by the prevailing wind and stored in the body for decades.

"Uranium can enter the body through inhalation, ingestion, or direct contamination of open wounds. The health consequences are confined primarily to the organs of concentration: lung, kidney and bone." As a result, one severe health impact is a potential loss of kidney function. (Highly Enriched Uranium Working Group Report, U.S. Department of Energy, December 1996, page 5). Helms-Hughes' mother and an aunt both grew up on that same ancestral land and both died in renal failure.

III. AREAS OF CONCERN

A site-specific Environmental Impact Statement (EIS) to analyze impacts from the BLEU Project to human health, safety, and the environment has not been performed. As stated in the "Environmental Assessment (EA) on Proposed License Amendments to Special Nuclear Material License No. SNM-124 Regarding Downblending and Oxide Conversion of Surplus High-Enriched Uranium" (June 2002), airborne emissions of uranium and thorium will increase four to five times current levels. In addition, NFS's hydrogen and nitrogen oxide emissions from the BLEU Complex will nearly double when added to their existing airborne releases. Radiological impacts from the proposed BLEU Project operations also would include the release of plutonium, americium, actinium, and lesser quantities of fission products including technetium, cesium, and strontium.

NFS claims that the added airborne effluent from the BLEU Project will not have a significant impact on human health or the environment outside NFS's protective fence. Helms-Hughes disagrees and maintains that the additional airborne contaminants will increase the health risks for herself, her family, her community, and other towns and counties in NFS's Zone of Interest.

Helms-Hughes respectfully requests that a site-specific EIS be performed to analyze impacts to human health and the environment. Helms-Hughes maintains that the lack of availability of comprehensive scientific data

to determine the presence of a potential cancer cluster located within one-half mile of the NFS plant, is one reason to require an EIS.

A. Data to evaluate Appalachian cancer risks is lacking

According to an August 29, 2003, study prepared by East Tennessee State University in Johnson City, Tenn., (located in the town next-door from Erwin, Tenn.), entitled "Environmental Exposure Database Development for Appalachian Region Counties in Kentucky, Tennessee and Virginia," researchers attempted to develop a database of environmental exposure sources in the Appalachian counties of Kentucky, Tennessee and Virginia. This project was part of the Rural Appalachian Cancer Demonstration Program, which is addressing regional cancer disparities. According to the report, factors such as the rate of exposure, duration of exposure, and magnitude of the exposure affect the potential for the development of cancer and must be understood to address the role of environmental exposure in development of cancer. It is also important to realize that data linking specific chemicals to cancer in humans are not available. Chemicals listed as human carcinogens are done so based on animal studies or epidemiological data. Data linking a chemical directly to a specific pathology are not available. Based on these factors, ETSU evaluated the availability of data necessary to address the role of the environment in cancer rates in rural Appalachia.

The report states, "Although data exist that suggest rural Appalachian counties may have environmental releases of chemicals that are higher than the national norm, data necessary to evaluate that risk are lacking. We found that significant data gaps exist that need to be addressed before attempting to link these apparently high exposures to the occurrence of cancer. The data missing include information about the potentially exposed populations such as occupation and lifestyle choices (e.g., diet, smoking). The data on specific sites and releases do not contain the detail necessary to address potential exposure pathways, exposure concentrations and rate of exposure. Although the region selected for this study was a subpopulation of the entire Appalachian region, it was too large to collect the data necessary during the one-year duration of this project. We have concluded that the data necessary to address the role of environmental exposure are not available. We have recommended that a longer-term focused county-specific study be used to address these issues.

"We recommended that one or two counties with high cancer rates and appropriate control counties with cancer rates similar to the national norm be selected for this study. The study would focus on gathering detailed information about the population and potential exposure sources to develop a model for application to the entire Appalachian region. Based on the data, we suggested that a limited number of counties do have high cancer mortality rates and a correspondingly high number of hazardous waste sites. These counties would be attractive candidates for more intense scrutiny to determine if a link between environmental exposures and the high cancer

mortality rates might occur." (Exhibit 1)

B. Cancers located within immediate vicinity of NFS

There is no scientific data available at present to determine whether residents living adjacent to, near, or downwind from NFS are at an increased risk of cancer due to chemical and radiological releases. However, an illustration of cancer cases on streets located within a half-mile of NFS begs further investigation, if only to disprove what appears obvious. (Names of the cancer victims have been withheld.)

On Washington Street, three members of one family died of various types of cancer, including: esophagus, colon, throat and face cancer. A fourth member is a survivor of eye cancer. This entire family lived a quarter mile from NFS, on the corner of Carolina and Washington streets.

Other Washington Street residents also died of various forms of cancer, including: two from lung cancer , chronic lymphocytic, two from colon cancer, non-Hodgkins lymphoma, two from stomach cancer, and one each from breast, head-and-throat cancer. Survivors include one victim of colo/rectal cancer and another resident currently undergoing treatment for stomach cancer.

Adams Street: One resident currently is fighting T-Cell Lymphoma.

Stalling Lane: One death from brain tumor.

Harris Street: One death from lymphoma.

Sycamore Street: One death from bone cancer, one from cancer (type unknown), one from breast cancer. In addition, one woman on the street is a survivor of breast cancer, one man is a survivor of esophageal cancer, and another is fighting esophageal cancer.

Luttrell Street: One death from a rare form of cancer and another from cancer (type unknown).

Love Station: One death from cancer (type unknown).

C. Allegations of withholding information from NRC

A former Framatome engineer has filed a formal complaint with the Nuclear Regulatory Commission in regard to construction of the BLEU Project. The Allgegation Report is filed as RII-2003-A-0168. Unfortunately, that report, which was filed in November 2003, has not been made publicly available on the NRC's public information docketing system.

According to the author of the complaint (whose name is being withheld here but should be readily available to the NRC), NFS withheld some pre-construction ground contamination survey information from a neighboring resident. The survey was performed by Law Engineering of Knoxville and indicated that there could be contamination on the resident's property and the CSX Railroad property as well.

The author of the complaint indicates that the local building inspector requested Framatome ANP (FANP) get CSX railroad to issue a letter which stated that they agreed construction at the BLEU facility would not impact their railroad yard. *"CSX responded that they would not agree to that until FANP paid for an independent civil engineering analysis of the site. FANP did not want to spend the money so they ignored all the requests and the problem went away,"* he said.

The complainant said he quit work with FANP *"after a big battle with management over the way they were forcing the design team to play dumb with the NRC and steer them away from 'weak' areas in the system. ... I have filed a formal complaint against FANP management with the NRC and it is supposedly under investigation. The gist of my complaint is that FANP management purposely altered construction criteria after discovering that it was ignored by the contractor,"* he told Helms-Hughes.

The complainant also spoke of design issues which warrant thorough investigation by the NRC. According to the complainant, the NRC is required to sign off on the final design, construction and start-up testing plan for all Category III nuclear fuel fabrication facilites (i.e. BLEU project). A series of meetings between NRC, NFS and Framatome was held from February 2003 to May 2003 to assess the readiness of the BLEU facility. The end result was that NRC agreed that the plant was safe and ready.

According to the complainant, *"The criticality detection system is not installed to prevent a nuclear accident. Its purpose is to create a plantwide audible alarm in the event of a nuclear accident. During an accident of this nature, radiation levels can be high enough to be lethal to those exposed in a matter of seconds. The purpose of the alarm system is to warn ALL personnel in the plant to RUN to the plant boundary and thus limit the exposure. The system is a license requirement, but considered a last resort and expected never to be used,"* he said.

"The detection system is composed of detectors, logic devices and audible alarms. Early in the design process NFS required the FANP design team to use detectors which were identical to those used at NFS. NFS stated that this was necessary for ease of calibration and testing. This made perfectly good sense, however, I was against using these Eberline devices because they had never been 'burst' tested according to ANSI 8.3.

"ANSI 8.3 is the American National Standards Institute document which defines the performance and testing requirements for these systems. It was adopted by NRC many many years ago and was most recently revised in 1986. Therein is a requirement that all equipment associated with these systems be 'burst' tested at radiation levels comparable to those expected during an actual incident. This is a sensible requirement because it is a well-documented phenomena that low-voltage silicon components can experience increased failure rates when subject to extreme neutron and gamma fields. However, burst testing is an expensive and difficult proposition. There are very

few places available where these levels of radiation can be attained.

"NFS agreed that it was a valid issue and arranged to have Los Alamos burst test the selected detectors, logic devices and audible alarms. Richard Ratner of NFS took three of the Eberline detectors/logic devices and three of the Federal Signal audible alarms to Los Alamos and witnessed the test. Apparently the devices were subjected to three different levels of radiation. I'll call them high, very high and extremely high. The logic devices functioned adequately during the high radiation test, but failed to work during the very high and extremely high test," he said.

"Once it was determined that the detectors would not work at these very high radiation levels, the criticality experts (Nuclear Safety Associates) were called in to estimate via calculation the expected radiation levels during one of these accidents. This was done by modeling the uranium solution to determine the strength of the radiation source and also modeling the physical properties of the tanks and building to determine the sheilding properties. Shielding refers to the fact that tanks and building walls can act as shields which effectively attenuate the radiation and maybe reduce it from very high to just high," the complainant said.

"The model used for the shield assumed that the block walls inside the BLEU facility were solid concrete. They were supposed to be constructed with CMU blocks with the voids filled with concrete. During one of my visits to Tennessee, the workers were making a duct penetration through one of these walls and they showed me that they were far from totally filled with concrete. They were barely half filled, with many air gaps and spaces. I reported this to the project manager, Nak Urza, and his comments were that it didn't matter anyway.

"As far as I know, NFS and NRC are unaware of the situation with the block wall. I refused to sign the paperwork attesting that these walls met the construction specification. Michael Lance, also of FANP, also refused to sign off on this paper work. Nak Urza rewrote the performance criteria and signed off on the paper work. I am certain that the radiation calculations were never re-run with a more accurate model in place. And I am also certain that there is no valid documented proof that the system logic devices are in an area where the maximum expected radiation level is less than their failure point.

The construction company tried to fill the voids, but were unaware of the importance of the problem. They thought it was a structural requirement," the complainant has alleged.

D: Concerns regarding the ISA Summary

The Non-Proprietary Version of the Integrated Safety Analysis (ISA) Summary for the BLEU Project Oxide Conversion and Effluent Processing Buildings raises several concerns.

Page 44: Why isn't the fire resistance rating of the barrier (wall) between the Oxide Conversion Building and the Effluent Processing Buildings defined as it is for all other walls? Shouldn't it be three hours, like the OCB

process?

Sect 2.10: Statements are made about ANSI compliance of the criticality detection system, but this is in question based upon the complainant's NRC Allegation Report RII-2003-A-0168. This allegation should also bring into question the adequacy of the construction quality verification measures (i.e. density of concrete walls deviating significantly from the numbers used in the design calculations).

General question: Were the uranium transportation and storage systems at BLEU designed with any anti-terrorism features added? Shouldn't some of these bounding accident scenarios be reviewed by Homeland Security to ensure that the latest protections are utilized? For example, the document states that railroad cars meet Department of Transportation CFR49, which calls for cars to meet a 1981 standard.

Section 2.0 Facility Description: There is no mention of the Leonard property next door to NFS. The distance to the nearest residence (450 feet) is questionable, and may not be an accurate representation of the distance to the property line, but rather the distance to the actual residence.

Buzzwords: The ISA Summary uses some industry buzzwords such as "Item Relied On For Safety," "Double Contingency" and "Active Engineered Controls," but nowhere does it define any fault tolerance requirements for these systems.

E. Decommissioning

On Jan. 16, 2004, the Department of Energy (DOE) published a notice of availability of an EIS for the West Valley Demonstration Project, located on the Western New York Nuclear Service Center (also referred to as the Center). The Center comprises about five square miles in West Valley, New York. The Center was the site of a commercial nuclear fuel reprocessing plant, which was the only one to have operated in the United States. The Center operated under a license issued by the Atomic Energy Commission (now the U.S. Nuclear Regulatory Commission) in 1966 to Nuclear Fuel Services, Inc. and the New York State Atomic and Space Development Authority, now known as the New York State Energy Research and Development Authority (NYSERDA).

During reprocessing, spent nuclear fuel from commercial nuclear power plants and DOE sites was chopped, dissolved, and processed by a solvent extraction system to recover uranium and plutonium. Fuel reprocessing ended in 1972 when the plant was shut down for modifications to increase its capacity, reduce occupational radiation exposure, and reduce radioactive effluents.

In 1976, Nuclear Fuel Services estimated that over $600 million would be required to modify the facility to increase its capacity and to comply with changes in regulatory standards. As a result, the company decided to withdraw from the nuclear fuel reprocessing business and exercise its contractual right to yield responsibility for the Center to NYSERDA. Nuclear Fuel Services withdrew from the Center without removing any of the in-process

nuclear wastes. NYSERDA now holds title to and manages the Center on behalf of the people of the State of New York.

NFS has not adequately demonstrated financial assurance for the BLEU Project and decommissioning activities related to that project. On Nov. 13, 2003, NRC approved a financial assurance exemption for NFS and the BLEU Project. The NRC has accepted a letter of intent from the U.S. Department of Energy which would address decommissioning costs associated with the BLEU Project, finding that the ability of the U.S. Government to pay its obligations is at least equal to the ability of a private financial institution to honor a guarantee of funds through one of the other instruments specified in 10 CFR 70.25(f).

Perhaps the NRC is familiar with the phrase, "The Road to Hell is paved with good intentions." While it has been the intent of DOE to clean up its energy-related sites, that cleanup is far from "clean closure" and now amounts to cleaning up contaminants to "as low as reasonably achievable" and transfer of the site to DOE's Legacy Waste division for monitoring in perpetuity, with U.S. taxpayers footing the bill.

Given NFS's track record in West Valley, and DOE's haste to unload its legacy waste in an expeditious manner, it is not acceptable to saddle U.S. taxpayers with a letter of intent from DOE to clean up the NFS facility once this project is over. NFS's decommissioning costs should be made public so that the public can evaluate the adequacy of funding.

IV. CONCLUSION

For the foregoing reasons, Petitioner Helms-Hughes has demonstrated that she has standing to participate in this proceeding, and has submitted a number of concerns which must be addressed before the BLEU Project can go forward. Helms-Hughes respectfully requests the NRC require NFS to perform a full EIS to address the foregoing concerns; that NRC investigate thoroughly the allegations of the former Framatome employee; that ownership of NFS and monetary provisions for decommissioning be publicly disclosed, and that the NRC not foist cleanup costs onto the public by settling for DOE's letter of intent.

Respectfully submitted,

Kathy Helms-Hughes

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(Dated Feb. 2, 2004)

CERTIFICATE OF SERVICE

I certify that on Feb. 2, 2004, copies of Kathy Helms-Hughes' Third Request for Hearing were served on the persons listed below by e-mail transmission or facsimile, with paper copies and exhibit to follow in U.S. Mail.

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Environmental Exposure Database Development for Appalachian Region Counties in Kentucky, Tennessee and Virginia

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August 29, 2003

Exhibit 1

Executive Summary

Because many people fear cancer and many perceive that cancer risk is elevated by environmental causes, we attempted to develop a database of environmental exposure sources in the Appalachian counties of Kentucky, Tennessee and Virginia. This project was part of the Rural Appalachian Cancer Demonstration Program, which is addressing regional cancer disparities.

Factors such as the rate of exposure, duration of exposure, and magnitude of the exposure affect the potential for the development of cancer and must be understood to address the role of environmental exposure in development of cancer. It is also important to realize that data linking specific chemicals to cancer in humans are not available. Chemicals listed as human carcinogens are done so based on animal studies or epidemiological data. Data linking a chemical directly to a specific pathology are not available. Based on these factors we evaluated the availability of data necessary to address the role of the environment in cancer rates in rural Appalachia.

Although data exist that suggest rural Appalachian counties may have environmental releases of chemicals that are higher than the national norm, data necessary to evaluate that risk are lacking. We found that significant data gaps exist that need to be addressed before attempting to link these apparently high exposures to the occurrence of cancer. The data missing include information about the potentially exposed populations such as occupation and lifestyle choices (e.g., diet, smoking). The data on specific sites and releases do not contain the detail necessary to address potential exposure pathways, exposure concentrations and rate of exposure. Although the region selected for this study was a subpopulation of the entire Appalachian region, it was too large to collect the data necessary during the one-year duration of this project. We have concluded that the data necessary to address the role of environmental exposure are not available. We have recommended that a longer-term focused county-specific study be used to address these issues.

We recommended that one or two counties with high cancer rates and appropriate control counties with cancer rates similar to the national norm be selected for this study. The study would focus on gathering detailed information about the population and potential exposure sources to develop a model for application to the entire Appalachian region. Based on the data, we suggested that a limited number of counties do have high cancer mortality rates and a correspondingly high number of hazardous waste sites. These counties would be attractive candidates for more intense scrutiny to determine if a link between environmental exposures and the high cancer mortality rates might occur. An important factor for selecting the counties for these studies should be an identified higher than expected rate for a specific cancer.

Report Overview

Appalachian communities fear cancer. Many communities and their leaders ascribe their perceived elevated cancer risk to environmental causes. This report is framed to describe the process and questions raised in attributing higher than average cancer deaths to environmental causes. The report is written to provide some initial data findings and as a primer on environmental epidemiological approaches that would need to be addressed to answer community beliefs and concerns.

One of the major objectives of the Rural Appalachian Cancer Demonstration Program was to aggregate existing cancer data sets across state borders. Compiling these data sets facilitates exploration of regional cancer disparities through an analysis of data patterns both within the region and in comparison with areas outside the region. One of the high priority data sets for this objective was aggregation of existing data that characterizes environmental exposures that may be cancer risk factors. This prioritization is in response to the documented higher than average level of released potential environmental contaminants in this region ().

To address the role of environmental exposures in the development of cancer, several things are required. Factors such as the rate of exposure, duration of exposure, and magnitude of the exposure affect the potential for the development of cancer. First, a source of carcinogen must exist, second, a pathway from the source to the receptor organism (human populations) must exist, and third, sufficient exposure duration and concentration must occur. Our goal was to aggregate existing datasets that would document some aspects of this pathway by which an environmental toxin may become a cancer risk factor. It is also important to realize that data linking specific chemicals to cancer in humans are not available. Chemicals listed as human carcinogens are done so based on animal studies or epidemiological data. Data linking a chemical directly to a specific pathology are not available.

An initial assumption made when preparing the proposal was that databases of environmental related exposures were available. We found that while data exist in several sources, they are often incomplete, out-of-date or missing, and not available in easily transferable formats. Federal and state laws significantly impact the quality and completeness of available data. Regulations mandate what information needs to be collected and what does not, how environmental exposure sites are categorized, and what information is publicly available. The quality of available data for this region should improve as the quality and comprehensiveness of the new national databases are improved.

The first step in documenting an environmental exposure pathway is simply to determine sites where an environmental contaminant may pose an exposure risk. We tried to compile information on exposures from national and state identified Superfund sites, which are only a small number of the total possible environmental exposures sites. Even at these sites, data availability and quality was inadequate to the task of linking environmental exposures to potential cancer risk.

We have completed a record review of each state's files on state and federal hazardous waste sites. Although we have not reviewed files from all sites we have reviewed sufficient files to make general comments about the quality and quantity of data available from each state. Despite the limitations on data quality and availability, we were able to aggregate some environmental exposure data. This report includes some preliminary regional mapping of these data and an initial overlay of these maps with regional cancer mortality rates.

It is clear that chemical releases are high in the Appalachian counties of Kentucky, Tennessee, and Virginia. The potential of these releases as cancer environmental risk factors can only be evaluated with quality, complete datasets that are aggregated at the regional level. Significant data gaps exist that need to be addressed before attempting to link these apparently high exposures to the occurrence of cancer in these counties.

Potential Scope of the Exposures

To provide a sense of national scope, illustrates the relative magnitude of total weight of chemical releases in the United States during 2001 by state. We divided the levels of releases into 5 groups (quintiles). Tennessee was in the group with the highest quantity of releases, Kentucky was in the second group and Virginia was in the third group. The higher than average level of released potential contaminants in this region is one of the key reasons we prioritized aggregation of data related to environmental exposures.

Figure Total pounds of chemicals released from all facilities in the United States during 2001 by state (Source: http://www.epa.gov/tri/tridata/tri01/index.htm)

Environmental Exposures and Cancer

To address the role of environmental exposures in the development of cancer several things are required. Factors such as the rate of exposure, duration of exposure, and magnitude of the exposure affect the potential for the development of cancer. First, a source of carcinogen must exist, second, a pathway from the source to the receptor organism (human populations) must exist, and third, sufficient exposure duration and concentration must occur to produce a defined pathological finding. Potential sources of carcinogen include occupational sources, natural sources, waste releases, household chemicals, and agricultural sources (e.g., pesticide applications). For exposure to occur a pathway from the source to the exposed person must be completed. Potential pathways include movement of the chemicals from the source to the person in air, water, soil, and food. Finally the source and pathway must provide an exposure concentration and duration necessary to achieve a harmful dose. Our goal was to aggregate existing datasets that would document some aspects of this pathway by which an environmental toxin may become a cancer risk factor.

Environmental Exposure Database Development

The primary objective of the environmental exposure assessment was to evaluate and develop a database that characterizes the environmental exposures. Sources of information about potential exposures include data from state and federal superfund records, discharge permits, Clean Water Act 303(d) lists, the Toxic Release Inventory, and emergency response plans. The Facility Registration System is a centralized database developed by the United States Environmental Protection Agency (USEPA, 2003a). When fully implemented the FRS will contain data about facilities, sites and places "subject to regulation or of environmental interest" (USEPA, 2003a).

An initial assumption made when preparing the proposal was that databases of environmental related exposures were available. We found that while data exist in several sources, they are often incomplete, out-of-date or missing, and not available in easily transferable formats. The following sections highlight some of our findings related to the collection and aggregation of a quality dataset on environmental exposures.

Availability and Transferability of Data

The effort to transfer quality data sets to a single Appalachian specific database will require more time and resources than allocated during this short-term project. Our assumption that certain datasets would be available for aggregation was based on information provided in several sources such as the Toxic Release Inventory, EPA's Enviromapper, and the Facility Registrations System (FRS). Furthermore, the assumption was that the data would be available in formats easily transferred to a database that could then be converted to maps using ArcView GIS software (ESRI, Redlands CA). What we found was that these assumptions were only partially true. Both data transferability and data quality were significant issues with most of these data sources.

Our initial approach was to perform a Web-based search to determine possible sources of data, with the intent to determine where data are available, what data are available and how the data might be obtained. We established quality criteria for data to be included in the database. Since the purpose of the database is to provide data that can be used in studies linking environmental exposure to cancer occurrence it is important that the nature of the contaminants (chemicals), their concentrations, the source matrix (e.g., soil, air, water, or biota), age of the source and current site status is available. The data sources used in this search are briefly described in .

Table Sources of data used to identify chemical exposures in the Appalachian counties of Kentucky, Tennessee and Virginia.

Data source	Location	Comments
USEPA Envirofacs data warehouse	http://www.epa.gov/enviro/index_java.html	Large searches not possible
USEPA CERCLIS Database	http://www.epa.gov/superfund/sites/cursites/index.htm	Dependent upon quality of report form facility or state
USEPA Facility Registration System	http://www.epa.gov/enviro/html/fii/index.html	Large searches not possible.
Agency for Toxic Substances and Diseases Registry (ATSDR 2003b)	Web based in health assessment reports	Limited
303(d) lists	Varies in each state	Little information on toxics
Toxics Release Inventory (TRI)	http://www.epa.gov/tri/tridata/tri01/index.htm	Selected chemicals and industries Requirements have evolved
Air Toxics Database	http://www.epa.gov/ttn/atw/index.html	Requirements have evolved

Many of the Web based sites, while initially appearing useful, do not allow for easy extraction of the data. This is especially true when the data needed are specific to the Appalachian counties in three states. For example, to obtain data for Tennessee, a list of sites is obtained by conducting an individual search for each county. So for Tennessee this would require 51 individual searches to obtain a list of sites. To obtain detailed information about each site in a county, a search of the county database would be required for each site. So for Hamilton County, Tennessee this would require 97 searches.

Based on the initial web based survey, we then attempted to focus on hazardous waste sites that were either on state or federal lists and perform a review of the files that are located in state regulatory agency files. We found that the quantity and quality of information contained in the files was variable. In many cases data or parts of files were missing. Each state (Kentucky, Tennessee and Virginia) used different systems to maintain files and access to the files was not always easily accomplished. In one regional office we were allowed to review no more than two files per day, since that office contained more than 100 sites we would need to devote a minimum of two months with daily visits to review these files. Since this office is several hundred miles from the ETSU campus this would require significant costs and time.

Impact of Federal and State Regulations

Federal and state laws significantly impact the quality and completeness of available data. These regulations mandate what information needs to be collected, how environmental exposure sites are categorized, and what information is publicly available.

The regulation of hazardous waste generation, handling and disposal is covered by a large number of federal and state laws. The most commonly cited legislation when discussing hazardous chemicals released into the environment are The Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) also known as superfund. Generally, states are responsible for the enforcement of these regulations under the review of the United States Environmental Protection Agency (USEPA). Responsibility for oversight of remediation of national priority list (NPL) sites is assigned to the USEPA. Sites are placed on the NPL based on an extensive review process that is described in CERLA and associated amendments. Basically, data collected by the USEPA, state agencies and contractors are used in a mathematical formula known as the hazard ranking system (HRS). Any site that receives a score of 28.5 or greater is ***considered*** for inclusion on the NPL. The final decision about inclusion of sites on the NPL is made using a rulemaking process that includes public comments (USEPA, 1999; USEPA, 2002). The USEPA will only place sites on the NPL that cannot be addressed using other regulations, such as RCRA. Sites listed on the NPL are typically those where the owner is bankrupt or uncooperative. Congress intended the states to take responsibility for oversight of hazardous waste regulations; this is done with the approval of the USEPA. The USEPA will provide funds only for sites that are placed on the NPL (USEPA, 2002). Information about sites or spills that are regulated under CERLA is entered into a USEPA managed database known as CERCLIS.

States are charged with developing a management program that is consistent with the federal rules. The USEPA reviews these plans and determines if they are consistent and equivalent to the federal rules. When the USEPA determines that a state's program is equivalent to and no less stringent than the federal regulations, the state is listed as an authorized state and assumes all responsibility for regulation of hazardous wastes in the state (USEPA, 2002).

Another important agency is the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is responsible for addressing how hazardous substances in the environment affect the public health. ATSDR meets this responsibility by conducting public health assessments of waste sites and health consultations concerning specific hazardous substances. ATSDR also maintains health surveillance programs and registries. ATSDR personnel respond to emergency releases of hazardous substances, conduct applied research in support of public health assessments, and disseminate information concerning hazardous substances (ATSDR 2003a). In some cases sites that are subjected to an ATSDR public health assessment may be placed on the NPL (USEPA, 2002).

Data Quality

Several additional factors impact data quality, including time delay in the availability of data, which data are reported, and incomplete information about exposure pathways and concentrations of contaminants. The quality of available data for this region could improve as the quality and comprehensiveness of the new national databases are improved.

An important limitation to current data sources is the time delay in the availability of the data. For example at the time of preparation of this report the latest Toxic Release Inventory data are the 2001 data. A search of the FRS system on July 16, 2003 resulted in a record identifying Texas Instruments in Johnson City, Tennessee, as a local facility. Texas Instruments has not operated that facility for several (greater than 5) years. Other similar examples could exist in the Appalachian region.

Another limitation is that the amount, quality and type of information stored in the available databases are variable. The CERCLIS hazardous waste site database lists contaminants for some sites, but it does not list concentrations and gives little information about exposure pathways. The requirements for which data are reported are changing. For example the USEPA reported in the Executive Summary of the 2001 Toxic Release Inventory Public Data

Release (USEPA, 2001), that the reporting threshold for lead was lowered in the 2001. This brings into question the usefulness of data collected and reported before 2001 since many releases might not have been reported because they were below the threshold. This same issue applies for other reportable chemicals. Changes to the list of reportable chemicals were made in 1988, 1991 and 1995. Additionally, there are more than 650 reportable chemicals under the TRI; determining exposure to these chemicals for any individual or population is at best difficult and in many cases impossible (USEPA, 2001).

The development of searchable databases is an active ongoing program and new sources are being developed and improved. The quality of an Appalachian region specific database should improve as the new databases are brought on-line and improved. The development of a useful database suitable for relating cancer rates to environmental exposures would require at least two additional years of effort.

Case Study: Documenting Superfund Sites

The first step in documenting an environmental exposure pathway is simply to determine sites where an environmental contaminant may pose an exposure risk. We tried to compile information on exposures from national and state identified Superfund sites, which are only a small number of the total possible environmental exposures sites. Even at these sites, data availability and quality was inadequate to the task of linking environmental exposures to potential cancer risk.

Available Information

Based on file reviews, the information provided in was compiled about the number of sites listed in the Comprehensive Environmental Response, Compensation and Liability Information System (CERCLIS) database. CERCLIS is the data management system that the USEPA uses to track activities at superfund sites considered for remediation. A searchable version of CERCLIS is available on EPA's superfund web page (USEPA, 2003c). We have also noted the number of sites that are on the National Priorities List (NPL). The NPL is the list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants and is used by the USEPA as a guide in determining which sites warrant further investigation.

Table Summary of the number of superfund (CERCLA) and NPL sites in the Appalachian counties of Kentucky, Tennessee and Virginia.

State	CERLIS	NPL	No Remedial Action
Kentucky	**169**	**2**	**140**
Tennessee	**114**	**4**	**288**
Virginia	**104**	**2**	**60**

Data Quality and Availability

The information in the files varies from very complete to minimally useful. In the best files a list of identified contaminants of concern (chemicals), location of chemicals (e.g., storage), type of releases (e.g., through air, water, soil etc.) and concentration are included. In most cases there is no clear identification of which chemicals are of greatest concern. Many of the files do not contain information about the data quality, which adds uncertainty about the validity of the few concentrations reported. This prevents us from accurately quantifying the exposure concentration and rate. In some cases contaminants are listed but their location on site is not given. Therefore, it is unclear if they are stored, in the soil, water or air. This prevents us from identifying which exposure pathways contain the chemical of concern. And in other cases the contaminants are not identified. This poses significant problems linking the site to any environmental or human health risks.

Challenges by State

Kentucky. Kentucky has a centralized Superfund office in Frankfort. A Freedom of Information "Open Records" form was required to obtain the state list. A disclaimer on this form reads "public files in regional offices are not necessarily complete." Phone calls to the Regional office and Frankfort revealed that Superfund information is

available only at the Frankfort office, yet the state Web page identifies local information repositories such as courthouses and libraries. To review files in the Frankfort office an open records form identifying the sites we wished to review was sent to Frankfort. The Frankfort office then had three days to respond to the request and set an appointment time.

In Kentucky there are 169 sites on CERCLIS, two sites on the NPL and 396 sites identified by the state. Kentucky has listed 140 sites where there is no further remedial action planned, eight sites have been deferred to oversight under the Resource Conservation and Recovery Act (RCRA). RCRA was enacted in 1976 to address the large and increasing amount of solid wastes generated in the United States (USEPA 2002). RCRA addresses the generation, storage and disposal of solid wastes, hazardous wastes. RCRA also addresses underground storage tanks (USTs).

We were able to locate a list that identified contaminants for 12 of 25 sites.

We completed file reviews on 25 sites; this review included active sites. Most site records indicated that no action was ever taken except sampling. Based on the sampling results state staff determined that the sites pose no significant risk to the environment or human health and therefore no remediation (clean-up) is necessary. All documentation typically pertained to a site's designation within the state classification system, predominantly as a "potential" hazardous waste site. To indicate that a site was under state or federal control, a green dot indicating the appropriate designation was placed on the file. There was no distinction between the state and federal documents contained in these files.

None of the files reviewed contained information about Phase I or Phase II site investigations. Phase I site assessments are used to identify the existence of potential environmental and public health risks at a site. In the Phase II assessment the magnitude or significance of any risks identified in the Phase I assessment are addressed.

Information about superfund sites in Kentucky consisted of a single file or a series of brief files. State employees indicated that the superfund files contained all correspondence between the state and the USEPA. The state employees were not knowledgeable about any federal activities on these sites. Analytical Results were included in the file review and were sometimes summarized. It is important to note that files for at least 30 sites were missing from the file repository.

Tennessee. Superfund records are available in regional Tennessee Department of Environment and Conservation (TDEC) offices. Three of these offices (Johnson City, Knoxville and Chattanooga are located in the Appalachian counties of Tennessee. To review the files an appointment is required. There are 402 sites in the Appalachian region counties of Tennessee, 114 of these sites are included in CERCLIS, 4 are on the NPL and 288 sites are archived with no further remedial action planned. The quality of the information available varied between the regional offices. In many cases the data were not properly validated, material in the files was poorly organized, some material was missing, some material was placed in the wrong files and activities were poorly documented.

Virginia. Virginia does not have a centralized Superfund program. Location of the files depends upon state or federal jurisdiction. Files related to state regulated sites are available in regional Department of Environmental Quality (DEQ) offices, in hazardous waste, solid waste, water, air and complaint files. The local office controlling the sites in the Appalachian counties is in Abingdon. Files on EPA-led sites are located in Richmond.

The number of sites is fluid due to pending regulatory delisting decisions. There are 104 sites in the Appalachian region counties of Virginia in CERCLIS, 2 sites are on the NPL, 60 sites are listed as requiring no further remedial action and 5 sites deferred for Resource Conservation and Recovery Act (RCRA) enforcement.

The majority of the files for sites in Virginia that we planned to review had been sent to the USEPA regional office in Philadelphia, Pennsylvania. Generally the files that we did review were complete and contained analytical results, risk assessments and other documentation.

Accomplishments: Measuring Exposures

Despite the limitations on data quality and availability, we were able to aggregate some data, and begin to explore that data from a regional perspective. Two examples are provided below.

Hazardous Waste Sites

We have completed a record review of each state's files on state and federal hazardous waste sites. Although we have not reviewed files from all sites we have reviewed sufficient files to make general comments about the quality and quantity of data available from each state.

During the project period we were able to review 84 files for sites in the Tennessee counties, 23 sites in the Virginia counties, and 25 sites in Kentucky located in Appalachian counties. The number of sites identified for each state is illustrated in . Some of the files reviewed were large enough to require several folders. In some cases a site might be addressed in separate files. This usually happens when a spill has occurred and a spill-specific response and clean up

was initiated. This action would be considered as a different regulatory event from actions required due to storage or chronic releases.

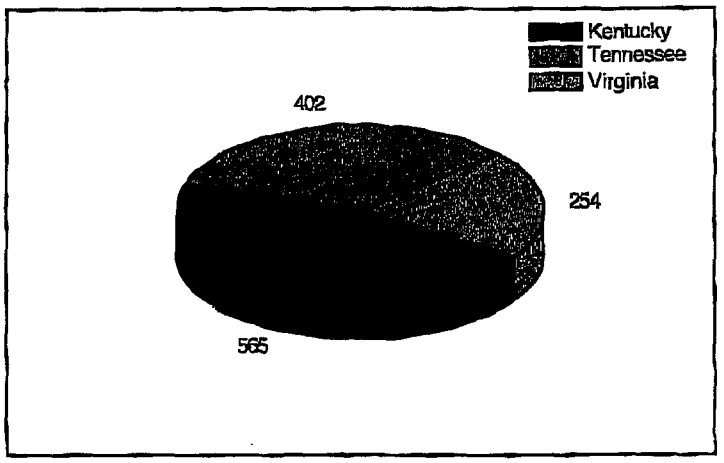

Figure Number of hazardous waste sites identified in Appalachian region counties in Kentucky, Tennessee and Virginia. Data are compiled from state and federal files (USEPA, KDEP, TDEC, VDEQ).
We have created a draft copy of a database using Microsoft Access (Microsoft Corp., Redmond WA) that contains lists and general information about the state and federal hazardous waste sites in the Appalachian counties in each state. We have also created a map using ArcView (ESRI, Redlands CA) that illustrates the number of sites in each Appalachian County based on data from state and federal files ().

Figure Map illustrating the number of hazardous waste sites in each county in the Appalachian regions of Kentucky, Tennessee and Virginia Data are derived from state and federal databases (USEPA, KDEP, TDEC, VDEQ).

Radon Exposure

An important ***natural*** environmental exposure is exposure to radon. Radon has been estimated to cause 21,800 deaths per year and is reported to be the second-leading cause of lung cancer. The greatest risk from radon exposure is in homes where cigarettes are smoked (Moore, 2002). Radon is a colorless, odorless gas that is a daughter product in the decay scheme of radium, which is commonly found in most soils. Radon potential is related to the geology and hydrology of a region. Radon is highest in uranium and phosphate ores and is found in significant but lower concentrations in limestone, shale and granite. Limestone and shale are common rocks found in the Appalachian Mountains.

As seen in and some of the highest potentials occur in the Appalachian region. The Map was developed using indoor radon measurements, geology, aerial radioactivity, soil permeability, and foundation type and the data are provided on a USEPA web site (USEPA, 2003d). Radon potential assessment is based on geologic provinces. The Radon Index Matrix is the quantitative assessment of radon potential. Geologic Provinces were adapted to county boundaries for the Map of Radon Zones. The risk from radon increases in zone 1, but is not absent in zone 3.

Figure Radon potential in Appalachian Counties of Kentucky, Tennessee and Virginia (USEPA, 2003d).

Figure . National map of radon zones (Source USEPA 2003d)

Accomplishments: Relating Exposures to Cancer Mortality

With full awareness of the limitations of our initial dataset, we attempted to overlay data on environmental exposures with cancer mortality rates. While no obvious patterns emerge in this preliminary analysis, we believe this approach is important to pursue in exploring cancer disparities in the region.

To compare the data on environmental exposures to cancer mortality rates, we created and . Close observation of and comparison to and demonstrates that there is no simple identifiable pattern shared by number of hazardous waste sites or radon potential and cancer mortality in the Appalachian counties.

Another form of analysis, a scatter plot chart, compares age adjusted cancer rates with environmental exposures as measured by the number of hazardous waste sites in each county. It becomes clear from that there is no observable relationship between number of hazardous waste sites and cancer mortality. It is important to note that the county with the highest number of sites falls in the middle of cancer mortalities. While the county with the highest cancer mortality rate, falls near the bottom of the number of sites (). The high cancer mortality might be a result of exposure to a single site releasing a large amount of chemical or even a small amount of a highly carcinogenic chemical. Another explanation might be that life-style choices, economic conditions or some undocumented site might be responsible for the high cancer mortality rate. High cancer mortality might also reflect quality of health care and economic status.

While these are very simplistic comparisons they are the only possible comparisons with the data that are available in the existing databases. It is possible that a relationship between environmental exposure and a specific type of cancer might still exist. The cancer mortality data used in and are for all cancers. For example, a more specific comparison for radon exposure could examine lung cancer in the high radon potential areas vs. low radon potential areas. Also, a better comparison might be to compare exposure to cancer incidence rather than mortality. This is not currently possible in either Tennessee or Virginia; neither state has a CDC approved Cancer Registry.

Figure Map of age adjusted cancer mortality rates (1994 – 1998) in the Appalachian counties of Kentucky, Tennessee and Virginia.

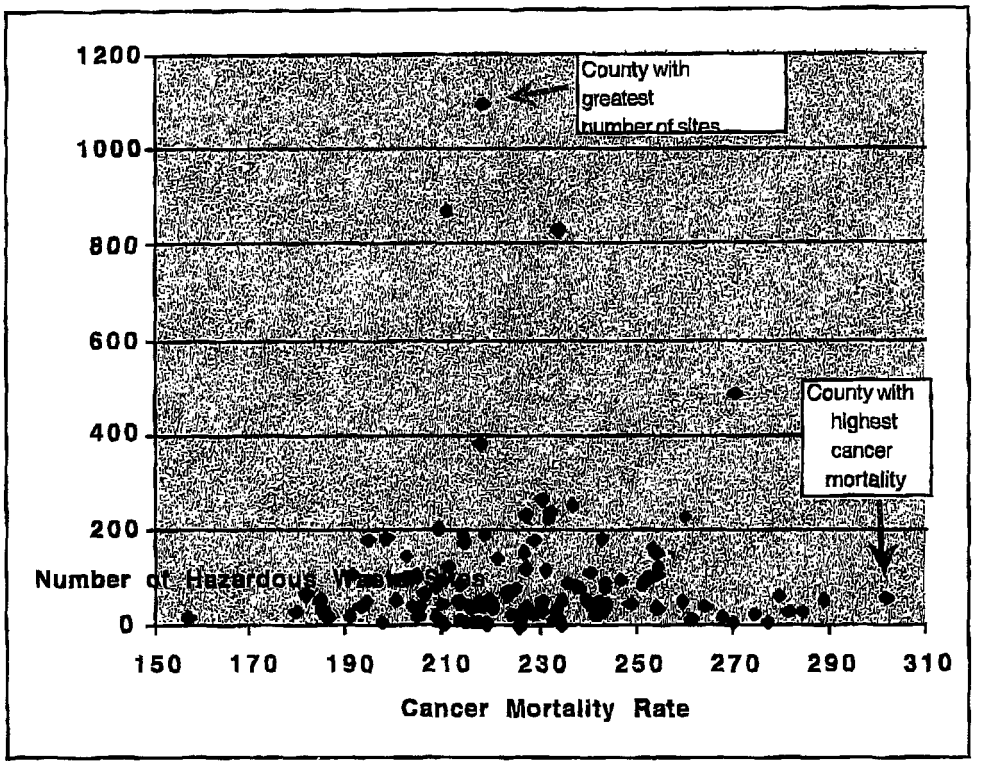

Figure Scatter plot of number of hazardous waste sites in a county vs. cancer mortality rates for 1994 – 1998.

Implications of Results

Although Kentucky, Tennessee and Virginia each ranked in one of the top three categories in total chemical releases during 2001 and radon exposure potential is high, the data necessary to demonstrate that this leads to exposures sufficient to cause cancer are lacking. Cancer occurs as a result of a long-term exposure to carcinogens. These exposures occur in the home and workplace. Additionally certain lifestyle choices such as smoking, high fat diet, and lack of exercise are known to play a role in the development of cancer (). Radon is not the only potential carcinogen that originates from natural sources related to the geology and climate of particular regions. Factors such as the rate of exposure, duration of exposure, and magnitude of the exposure also play a role in the potential for the development of cancer.

While high rates of release and large numbers of sites might lead us to the assumption that environmental releases are responsible for some of the observed high rates of cancer and other diseases, proving this using sound scientific and statistical methods is difficult because of the large number of uncertainties about confounding factors (e.g., life-style, life-long exposures, and genetic susceptibility). The available data do not provide useful information about which contaminants are released, which exposure pathways are completed (i.e., result in transport of contaminant from the source to the target populations) and how long those exposures have occurred. Additionally, in many of the high release areas it is likely that a large proportion of the exposed population is exposed because they work at the facilities responsible for the releases. This can lead to an over or under calculation of the number of non-occupational environmental exposures. Our review of the state files indicates there may be quality questions regarding the data provided in the online databases that are built using data reported by the facility operators and state regulatory agencies.

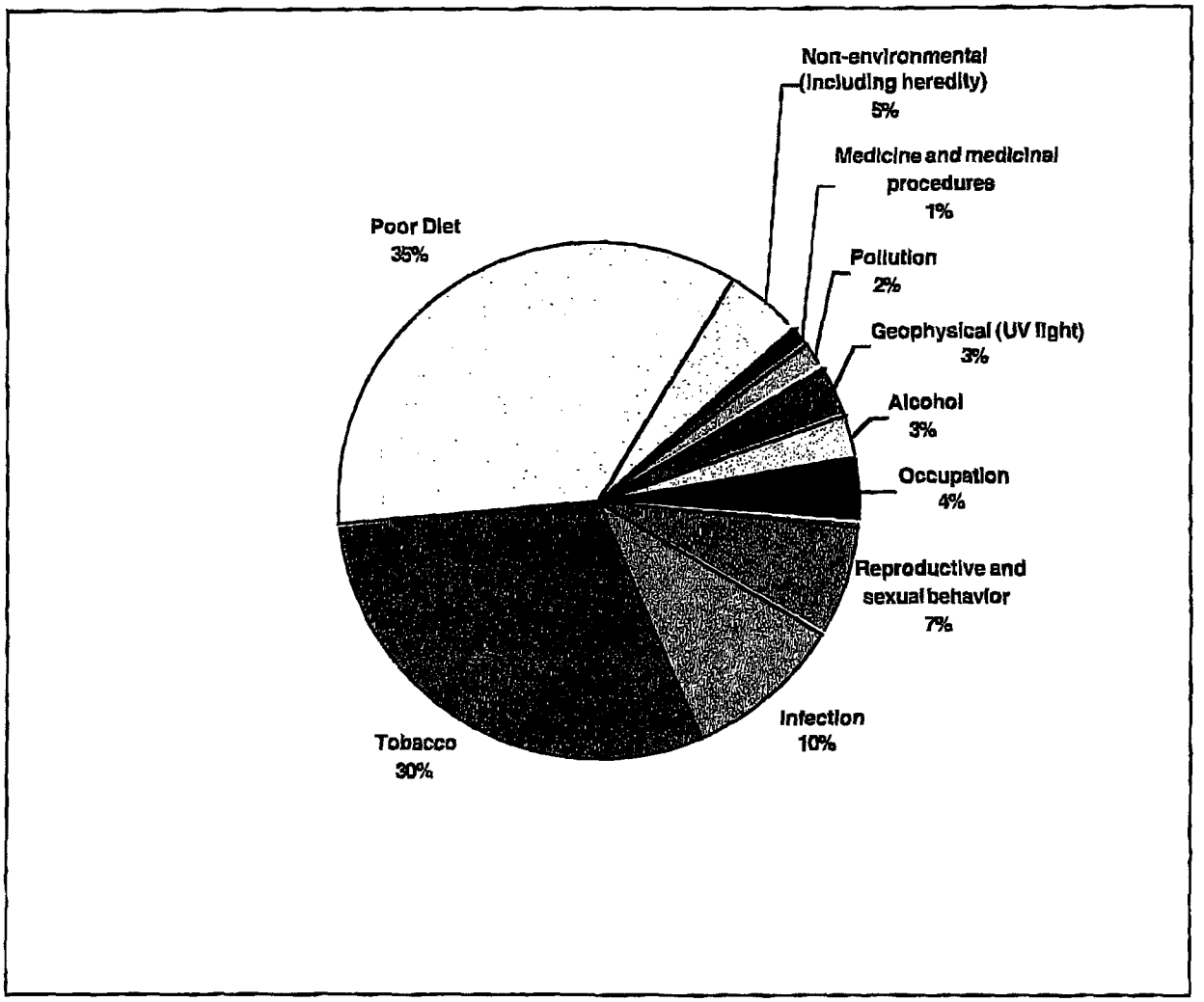

Figure Percent of cancer deaths associated with environmental and life-style factors (Adapted from Moore, 2002, p 135).

Limitations

We are not able to address the significance of environmental exposure in the development of cancer because there are gaps in the availability and quality of data. We were not able to evaluate other sources of data on toxic chemicals such as pesticide releases, small quantity waste generators, and transportation related releases. Nor are we able to evaluate the interaction of possible etiologic factors. The only natural exposure source identified and evaluated was radon.

Summary and Conclusions

Based on industrial chemical releases we have presented data that indicate chemical releases are high in the Appalachian counties of Kentucky, Tennessee, and Virginia. Significant data gaps exist that need to be addressed before attempting to link these apparently high exposures to the occurrence of cancer in these counties. Although the region selected for this study was a subpopulation of the entire Appalachian region, it was too large to collect the data necessary during the one-year duration of this project.

Specific issues that need to be addressed include:

Questions exist about the quality of the data available. Close scrutiny of the quality of available data, to eliminate poor quality data.

Identification and characterization of the releases should include
List of chemicals released
Concentration and rate of release
Release pathways (e.g., air, surface water, groundwater, soil, biota).
Extent of migration within the pathways
Characterization of the potentially exposed populations

1. Occupation
2. Length of residence in exposure area
3. Life-style characteristics (diet, smoking status)
4. Age and gender
5. Exposure to multiple carcinogenic factors

Characterize cancer incidence rates for specific cancers
There is clearly a significant amount of effort still required to provide a database that allows us to assess the role environmental exposures play in the development of cancer in the Appalachian region. Better coordination and communication is badly needed between state and federal agencies regarding activities on state and federally regulated sites. The lack of knowledge about activities on federal sites by staff in Kentucky exacerbates the lack of information about sites and potential exposures.
Recommendations
Data consolidation from existing sources requires one to two more years and should continue.
Data on pesticide use and exposures should be collected and added to the database.
Conduct more specific studies in rural Appalachian counties. Select one or two counties with high cancer rates and appropriate control counties with cancer rates similar to the national norm and focus on gathering detailed information about the population and potential exposure sources to develop a model for application to the entire Appalachian region. Careful examination and comparison of and shows that a limited number of counties do have high cancer mortality rates and a correspondingly high number of hazardous waste sites. These counties would be attractive candidates for more intense scrutiny to determine if a link between environmental exposures and the high cancer mortality rates might occur. An important factor for selecting the counties for these studies should be an identified higher than expected rate for a specific cancer.
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