Cancer Incidence in the Vicinity of the Site of

a Former Nuclear Facility Located in Apollo, Pennsylvania

A report by:

Steve Wing
Associate Professor of Epidemiology
The University of North Carolina at Chapel Hill

Declarations

1) The firm of Motley Rice LLC asked me for my opinions regarding cancer incidence in the vicinity of the former site of the Apollo nuclear facility. They provided financial support for Kaitlin Kelly-Reif, a Ph.D. student in The University of North Carolina at Chapel Hill Department of Epidemiology, to assist me with conducting new analyses of cancer incidence using data from Pennsylvania's cancer registry. Ms. Kelly-Reif worked entirely under my direction. As of this date I have not requested or received any compensation for my work on this case. My hourly fee for testimony at deposition or trial is $500.

2) I hold a Ph.D. in epidemiology from The University of North Carolina, Chapel Hill, where I have been a member of the faculty since 1985. I have conducted original epidemiological research on humans exposed to ionizing radiation since 1988 when I took primary responsibility for a study of occupational exposures to radiation at the Oak Ridge National Laboratory. My work on radiation exposures at Oak Ridge, Tennessee facilities includes studies of uranium-exposed workers at the Y-12 facility (Richardson and Wing, 2006). I teach graduate-level courses in epidemiology and advise graduate students. My curriculum vitae provides information on my published research, grant funding, teaching and service.

3) Within the past four years I testified by deposition in one law suit: Waste Industries USA, Inc. and Black Bear Disposal, LLC vs. State of North Carolina and the North Carolina Department of Environment & Natural Resources, General Court of Justice Superior Court Division, Wake County, North Carolina. My testimony in that case was for the defendant.

Introduction

4) The Apollo nuclear facility was situated on the Kiskiminetas River in the town of Apollo, Pennsylvania, 35 miles east northeast of Pittsburg. The town is proximal to four other small boroughs and townships within a one mile radius of the former Apollo nuclear facility. Altogether this area constitutes five minor civil divisions with a population of approximately 9,632 persons in 2010.

5) From 1958 to 1983, the Apollo nuclear facility produced low-enriched uranium, highly enriched uranium, and thorium fuels under ownership of three different corporations: the Nuclear Materials and Equipment Corporation, the Atlantic Richfield Company, and the Babcock & Wilcox Company. Facility operations were numerous and varied, and included conversion of uranium hexafluoride gas to uranium dioxide powder, low- and high-enriched uranium fuel conversion, thorium fabrication, scrap recovery of uranium, production of fuel pellets, decontamination of equipment, volume reduction of radioactive wastes, and storage of contaminated materials.

6) The Apollo facility had a history of poor materials accountability. Not all known points where radioactive materials could be released from the facility were monitored, and materials could escape through other openings because the facility was not sealed (Ring, 2012). A fire in 1963 resulted in off-site releases of highly enriched uranium.

7) These unmeasured and unmonitored radionuclide releases suggest workers and community members were exposed to radioactivity from the Apollo facility. Although radionuclide releases from the nearby Parks nuclear facility have also been of interest, the Parks facility was designed differently, operated different processes, and did not experience a fire resulting in off-site releases. Because of the potential for human exposure to ionizing radiation, several studies have examined cancer incidence around both facilities, however some of these studies do not separate cancer rates around Apollo and Parks despite their differences in construction, nuclear materials processing, and releases.

8) This report A) summarizes three earlier cancer incidence studies that include the Apollo area, B) compares the studies' methods, C) presents an analysis of cancer incidence in the Apollo area based on government records, D) compares the results with prior studies, and E) evaluates the limitations of spatial studies relevant to interpreting the results. The new analyses show that excess cancer incidence in the Apollo area was masked in prior studies because of the analytic decisions of the authors. The discussion of cancer incidence analyses is followed by F) an evaluation of the evidence that uranium and uranium decay products are carcinogenic to humans.

A) Prior Studies of Cancer Incidence Near Apollo, PA

9) In 1996 the Pennsylvania Department of Health (PDoH) reported on cancer incidence in 15 minor civil divisions (MCDs) near the Apollo and Parks facilities. These consisted of five MCDs within one mile of the Apollo facility (Area 1a), three MCDs within one mile of the Parks nuclear facility (Area 1b), and seven MCDs adjacent to Areas 1a and 1b, referred to as Area 2. The PDoH study used Pennsylvania Cancer Registry data on cancer incidence and age-sex specific population counts from the 1990 US census. PDoH calculated standardized incidence ratios (SIRs) for all cancers for 1984-1992. The SIR is defined as the ratio of the observed number of cancer cases in the study area to the number that would be expected if the residents had experienced the age-sex specific rates of the population of Pennsylvania (or another standard population). The denominator of the SIR, the expected number of cancers in the study population, is defined as the sum of the product of the standard population age-sex specific cancer incidence rates and the age-sex specific person-year estimates for residents of the study area, where the person-year estimate is approximated by the number of residents in the study area in each year. An SIR of 1.0 indicates that the observed number of cases is equal to the expected number.

10) To assess whether persons diagnosed with cancer resided within the same MCD as their reported mailing address, PDoH examined case records from the 15 study areas and 18 surrounding MCDs. Zip codes from cases in the 33 MCDs were matched to municipal districts using geographic information systems and input from postmasters. The PDoH reviewed addresses of cases in the 18 MCDs neighboring the study areas because cases with addresses outside the study areas may have actually lived in the study areas.

11) After correcting for discrepancies between case addresses and the locations of their residences, the PDoH study reported an elevated SIR for all cancers of 1.15 ($p<0.05$) in the five townships surrounding the Apollo facility based on a comparison to the State of Pennsylvania.

12) Boice et al. conducted two analyses of cancer incidence in the Apollo and Parks areas (Areas 1a and 1b combined). Their 2003 study analyzed cancer incidence in Apollo and Parks between 1993 and 1997. Their 2009 study expanded this analysis through 2004. Although Boice et al. had records for incident cancers in the years 1990, 1991 and 1992 (Boice et al. 2009 Figure 2), they did not calculate SIRs for these years in either of their analyses.

13) In each analysis Boice et al. aggregated the MCDs nearest to the Parks and Apollo facilities, producing one pooled SIR for both locations. Like the PDoH, Boice et al. calculated SIRs using cancer incidence data from the PA Cancer Registry. They used 1990 population estimates from the US Census Bureau for the 1993-1997 SIRs and 2000 population estimates for the 1998-2004 SIRs.

14) Boice et al. used a different residential validation method than the PDoH. Unlike PDoH they did not review cancer case records in MCDs outside the study area, and therefore did not consider the possibility that persons residing in the study area could have had mailing addresses in more distal MCDs. Boice et al. only considered the possibility that persons residing outside the study area had mailing addresses within the study area. Neither of the studies by Boice et al. reported statistically significant excess incidence for all cancers.

B) Comparison of the PDoH and Boice et al. studies

15) PDoH reported a statistically significantly elevated SIR for all cancers combined in the 1984-1992 time period for MCDs nearest to Apollo, whereas Boice et al. reported no statistically significantly elevated SIRs for all cancers in the combined MCDs near Apollo and Parks during the time period 1993-2004. Because Boice et al.'s analyses differ in several ways from the PDoH's, the differences in their conclusions could reflect differences in the aggregation of MCDs for analysis, changes in SIRs over time, differences in the methods used to count observed cases, differences in the methods used to calculate expected cases, or a combination of these factors. The following paragraphs provide a discussion of the differences in approaches used by PDoH and Boice et al. Of particular note is that, unlike PDoH, Boice et al. did not separate Areas 1a and 1b, did not look for study area cancer cases that might have had addresses outside the study area, and used census-year population counts to calculate SIRs that were not centered on the census year.

16) The PDoH calculated SIRs separately for MCDs closest to the Apollo facility and the Parks facility. Table 6-b in its report shows that SIRs for all cancers were higher in MCDs near the Apollo facility than in those near the Parks facility, and this comparison held for both males and females. Both Areas 1a and 1b had higher SIRs than Area 2, most of which is further from the nuclear facilities than Areas 1a and 1b. As noted earlier, the area-specific SIRs are of interest because of differences in the construction and industrial processes at the two facilities as well as differences in their environmental releases of radionuclides. Additionally, the Apollo facility was immediately adjacent to a neighborhood of relatively high population density to the east of the facility. Despite this *a*

priori basis for interest in differences in cancer incidence between the two areas, Boice et al. chose to combine them without providing a rationale.

17) As the PDoH noted, there are residential geocoding errors in the PA Cancer Registry. Because addresses on registry case reports do not always correspond to a person's residence location, proper correction for misclassification of residence would reduce bias in the estimate of the SIR unless the misclassification of residence is evenly balanced between excluding cases that resided in the study area and including cases that did not reside in the study area. PDoH considered both possibilities by examining records of cancer cases with addresses in the eight MCDs closest the Apollo and Parks facilities (Areas 1a and 1b), seven adjacent MCDs (Area 2), and 18 more distal MCDs. Among 3,335 cancer cases chosen for residence investigation, the PDoH was unable to determine the residence location of 179 (5.4%). Although none of these was included in their SIR calculations, they note that 70 of these cases "potentially should be included into the Area 2 control group based on zip code" (PDoH p 32), implying that some of the remaining 109 excluded cases could have resided in Areas 1a and 1b.

18) In contrast, Boice et al. only removed cases from the study area "because mailing addresses in rural areas include 'rural delivery' (RD) and 'post office box' addresses for persons who do not always live in the same municipality where the post office is located" (Boice et al. 2003, p 681). Although they provide the numbers of cancer cases in Area 2 in their 2009 publication, Boice et al. did not include these cases, or cases with addresses in the additional 18 MCDs investigated by PDoH, in their study. Therefore Boice et al. did not consider the possibility that cancer cases with addresses outside Areas 1a and 1b could have resided in Areas 1a and 1b, and they provide no evidence that this situation did not occur. In their 2003 analysis, Boice et al. state that, "Twenty-one of the 935 mailing addresses (2.2%) could not be confirmed as being within or not within one of the eight MCDs" (Table 2, footnote c), suggesting that they dropped these cases from the study rather than assigning them proportionately to the study MCDs.

19) As noted above, accurate study population estimates are important for calculating the correct number of expected cancers for the study area. The Apollo area experienced a decline in population from 1990-2000 and from 2000-2010. Both PDoH and Boice et al. calculated SIRs that included intercensal years, however neither accounted for changes in population. This should not result in much bias for analyses of short time periods centered around the year of the census because the midpoint is usually a good approximation of the average across all the years. However, in their 2003 paper, Boice et al. applied the 1990 population estimate for the study areas to the years 1993-1997, when the population was smaller. As a result, Boice et al. overestimated the expected numbers of cancer cases in these years. Because these values are the denominators of the SIRs, Boice et al. underestimated the SIRs.

C) Analysis of cancer incidence in Apollo 1990-2004

20) PDoH and Boice et al. had access to individual cancer case records with address information for each case. These records are not publically available, however total numbers of incident cancers for all

age-race-sex groups for Pennsylvania MCDs are available for the years 1990-2004, which includes the last three years studied by PDoH and all the years studied by Boice et al.[1] Earlier cancer incidence data are not publically available. The following analysis considers incidence of all cancers in the five MCDs surrounding the former Apollo nuclear facility (Apollo, North Apollo, Vandergrift, East Vandergrift, and Oklahoma minor civil divisions), referred to as Area 1a in the PDoH study.

21) Population data for the Apollo area were obtained from the US Census Bureau decennial censuses of 1990, 2000 and 2010. Over this time period, the population in the Apollo area declined by approximately 12%. In order to calculate standardized incidence ratios which accurately reflected the declining population, intercensal estimates of annual populations were made by linear interpolation between the census years.

22) The publically available data used in this analysis do not include race-specific cancer incidence for minor civil divisions. Therefore, although non-white cancer cases were excluded from the studies reviewed above, they could not be excluded from the current analysis. This is not a problem because there is no reason to exclude non-white residents from a study of cancer incidence in an area with a history of releases of radionuclides from a nuclear facility. Therefore age-race-sex-year specific cancer incidence rates for the Pennsylvania standard population were multiplied by age-race-sex-year specific population counts for the Apollo area to obtain expected numbers of cancer cases, the denominators of the SIRs. Observed cancer incidence counts in each year from 1990-2004 for the Apollo MCDs (numerators of the SIRs) and statewide cancer incidence rates were acquired from the Pennsylvania Department of Health Epidemiologic Query and Mapping System. 95% confidence intervals (CI) of the SIRs were calculated assuming a Poisson distribution.

23) Between 1990 and 2004, 1,732 cases of cancer were reported to the Pennsylvania Department of Health Cancer Registry whose addresses were in the five minor civil divisions surrounding the Apollo nuclear facility. There were 1,058 expected cases based on the age-race-sex-year specific incidence rates for the State of Pennsylvania, resulting in 674 excess cases of cancer during the study period.

24) Table 1 shows that the age, race, and sex adjusted SIR between 1990 and 2004 for all cancers is 1.64 (95%CI 1.56 – 1.71). This represents a statistically significant excess of all cancers in the Apollo area compared to the state of Pennsylvania. The excess for males (1.75, 95% CI 1.64-1.87) is larger than the excess for females (1.52, 95% CI 1.41-1.62). SIRs were calculated for each time period based on prior studies. In every study period, there is a statistically significantly elevated SIR. From 1990 to 1992, a time period that Boice et al. excluded from their SIR analyses, the SIR for males and females combined indicates an approximate doubling of observed compared to expected cases (SIR = 2.09, 95%CI 1.90 – 2.28).

[1] These data were provided by the Bureau of Health Statistics and Research, Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations, or conclusions.

Table 1: Observed and Expected Cancer Cases in the Apollo area and age, sex, and race adjusted Standard Incidence Ratios with corresponding 95% Confidence Intervals: 1990-2004

	Males				Females				Total			
Study Period	**Obs**	**Exp**	**SIR**	**95%CI**	**Obs**	**Exp**	**SIR**	**95%CI**	**Obs**	**Exp**	**SIR**	**95%CI**
1990 - 1992	249	113	2.20	1.93 - 2.47	213	108	1.97	1.71 - 2.24	462	221	2.09	1.90 - 2.28
1993 - 1997	359	181	1.99	1.78 - 2.19	289	177	1.63	1.45 - 1.82	648	358	1.81	1.67 - 1.95
1998 - 2004	323	237	1.36	1.21 - 1.51	299	242	1.23	1.09 - 1.37	622	480	1.30	1.19 - 1.40
Total	**931**	**531**	**1.75**	**1.64 - 1.87**	**801**	**527**	**1.52**	**1.41 - 1.62**	**1732**	**1058**	**1.64**	**1.56 - 1.71**

D) Comparison with results of prior studies

25) Without access to individual cancer case addresses, residential validation could not be performed in the present study. If validation were to be performed, it would be important to apply a procedure such as the one used by PDoH, that considers the possibility of errors of inclusion as well as exclusion. Although Boice et al.'s re-classification failed to consider the possibility that cancer cases residing in the study area had addresses outside the study area, their proportionate reduction in observed case counts can be applied to this analysis of the Apollo area to evaluate, under an extreme assumption, the impact of residential misclassification. Boice et al. removed different proportions of cases for different time periods, and these values were applied to the new analysis reported above. Boice et al. (2003) excluded 30.3% of cases from Area 1a in the 1993-97 time period, and this proportion was applied to the observed case counts for 1990-1997 with their exclusion proportion of 11.3% for Area 1a applied to the 1998-2004 time period (Boice et al. 2007), resulting in an SIR of 1.25 (95%CI 1.18-1.32). Boice et al. (2009) also report that 15.8% of cases in areas 1a and 1b combined were incorrect in the years 1996-2004. If 30.3% of cases are removed in the 1990-1995 time period and 15.8% are removed in 1996-2004, the SIR for Area 1a for 1990-2004 is 1.26 (95%CI 1.19-1.32). The all cancer SIR for the Apollo MCDs is statistically significantly elevated during the time period 1990-2004 even with application of Boice et al.'s one-sided residence validation method.

E) Limitations of spatial cancer analyses for identifying effects of local pollutants

26) Although discrepancies between addresses and residential location are important and should be considered in these analyses, errors in residence coding should not distract from a more fundamental feature of this approach: it is insensitive to the impacts of local pollution sources on cancer incidence. MCD boundaries provide a poor basis for identifying distance between residences and the point of release of radionuclides to the environment at the Apollo facility. Parts of MCDs excluded from Apollo MCDs Area 1a are closer to the facility than parts of the areas included; this would not occur if data analyses were not limited by MCD boundaries. Even in an analysis based on MCDs, access to residence information for individual cases can be used to evaluate whether cancer cases in MCDs outside the study area lived just outside the area's boundary, possibly nearer to the facility than some cases within the study area, or farther away. Although PDoH and Boice et al. had such individual information, they do not report having investigated this possibility.

27) Even more important, distance of a person's residence from the Apollo facility is a poor proxy for individual exposures to radionuclides emitted by the facility. Distance does not take into account inhomogeneity of the direction and distance of transport of radionuclides, time spent at home, time inside vs. outside the home, exposures at work, school or other locations away from home, and does not take into account other behavioral and physiological factors that could influence uptake of radionuclides released by the Apollo facility. It is well-known that analyses based on government-defined spatial units such as MCDs can dilute exposure-disease relationships because current residential location is usually a poor proxy for historical exposures.

28) The weakness of the method of assigning residences to government-defined spatial units can be reduced by using smaller spatial units. For example, Hatch et al. (1990), in a study of cancer incidence near the Three Mile Island nuclear facility that was later re-considered by Wing et al. (1997), assigned cancer cases to "study tracts" created from census blocks. Census blocks are spatially smaller than MCDs, and could be used to substantially reduce the mixing of populations at different distances from the Apollo facility. Although Boice et al. (2003, 2007) had access to individual records and could have used this more sensitive approach that had been used previously by Hatch et al. in a study of cancer incidence in the same state, they did not report any analyses based on smaller Census Bureau spatial units (blocks, block groups or tracts).

29) Another weakness of the spatial analysis approach is migration. People who resided in the Apollo area during its period of active operation, 1958-83, may have had the greatest exposure potential, for example those who were nearby during the 1963 fire or during any other specific releases from the operating facility. The SIR analyses reviewed in this report include as putatively exposed (living in the 5 Apollo MCDs) people who moved into the area after the facility closed and people who were born after the facility ceased operation. SIRs for the Apollo area are based, in part, on observed and expected cancer cases for people aged less than 40 in 2004 who had not been conceived or born at the time of the early years of the facility's operation, 1958-1963. Additionally, the spatial approach to evaluating excess cancer in relation to Apollo releases cannot account for exposed people who moved away from the area and whose residence at the time of cancer diagnosis was in another part of Pennsylvania or another state. The declining population of the five Apollo-area MCDs, from 12,555 in 1980 to 10,954 in 1990, to 9,632 in 2010, suggests the potential for out-migration to lead to underestimation of the relationship between local pollution sources and cancer incidence with the spatial approach used in the studies reviewed here. Migration is a particular problem for diseases with long latencies between exposure and detection, such as many cancers.

30) Epidemiological studies typically evaluate evidence of a causal relationship between exposure and disease by comparing disease occurrence in exposed and unexposed groups. Higher disease occurrence in an exposed compared to unexposed group is taken as evidence of causation if the groups are the same with respect to other causes of disease. Therefore exposure classification is a key component of any epidemiological study. If exposure classification is poor, truly exposed people are misclassified in the unexposed group, and truly unexposed people are misclassified in the exposed group, diluting differences in disease rates. This occurs in spatial studies where municipal

boundaries are not designed to separate people according to their exposure to a pollution source (e.g. the Apollo facility), where residential distance is poor proxy for pollutant exposure, and where migration leads to the mixing of exposed and unexposed groups over long periods of time between exposure and disease occurrence.

31) Differences between exposed and unexposed populations in other causes of disease can also bias epidemiological studies. SIR calculations are used to adjust for age, race and sex differences between the study populations and the standard populations. Although these factors are important, the study and standard populations differ in other ways that cannot be evaluated using surveillance records.

F) Uranium and its decay products are carcinogenic to humans

32) As a radionuclide, uranium atoms are unstable and emit radiation as they decay. All isotopes of uranium are radioactive. The decay chain for U-238, the most common isotope, includes 13 other radionuclides, ending with lead-206, which is stable. U-238 and several of its decay products, notably radium-226 and radon-222, emit α-particles. U-235, which is enriched for use in nuclear fuels and weapons, emits α-particles and γ-radiation.

33) Judgments about the human carcinogenicity of physical and chemical agents are based on evidence from *in vitro* and animal experiments as well as human case studies and epidemiology. The International Agency for Research on Cancer (IARC), the part of the World Health Organization that specializes in cancer, ranks environmental agents according to evidence of their carcinogenicity. IARC's categories range from Group 4, "probably not carcinogenic to humans," to Group 1, "carcinogenic to humans." In 2012 IARC evaluated the human carcinogenicity of radiation based on diverse types of evidence. They assessed types of radiation as well as specific radionuclides.

34) IARC rates α-particles, β-particles, and γ-radiation, all of which are created by isotopes of uranium and/or their decay products, as Group 1 carcinogens. IARC concludes that "Internalized radionuclides that emit α-particles are *carcinogenic to humans (Group 1)*," (italics in original) and elaborates:

- α-Particles emitted by radionuclides, irrespective of their source, produce the same pattern of secondary ionizations, and the same pattern of localized damage to biological molecules, including DNA. These effects, observed in vitro, include DNA double-strand breaks, chromosomal aberrations, gene mutations, and cell transformation.
- All radionuclides that emit α-particles and that have been adequately studied, including radon-222 and its decay products, have been shown to cause cancer in humans and in experimental animals.
- α-Particles emitted by radionuclides, irrespective of their source, have been shown to cause chromosomal aberrations in circulating lymphocytes and gene mutations in humans in vivo.
- The evidence from studies in humans and experimental animals suggests that similar doses to the same tissues – for example lung cells or bone surfaces – from α-particles emitted during the decay of different radionuclides produce the same types of non-neoplastic effects and cancers." (IARC, 2012, p 274)

35) IARC notes that, "Uranium creates a relatively complex spectrum of radiological hazards, including external exposure to β-particles and γ-radiation, and internal exposures to α-particles, β-particles, and γ-radiation" (IARC, 2012 p 263). From this assessment it is clear that uranium and its radioactive decay products are human carcinogens.

36) IARC's evaluation appropriately considers evidence of carcinogenicity from a broad array of disciplines. This is particularly important in the case of uranium because of weaknesses in the evidence drawn from epidemiology. For example, one epidemiologic study cited by IARC shows that lung cancer was more strongly related to measures of external penetrating radiation than to estimates of lung doses from internally deposited uranium (Richardson and Wing, 2006). That study's ability to detect an association between uranium and lung cancer was compromised by inadequate information on the solubility of uranium compounds, dates of intake and biomonitoring for individual workers, and incident cancers (the study relied on death certificate diagnoses). In evaluating evidence of carcinogenicity of uranium it is important to consider insensitivity of epidemiological studies in the context of other lines of evidence, as reviewed by IARC (2012).

Conclusions

37) Prior studies of cancer incidence in the MCDs surrounding the former Apollo nuclear facility were conducted based on flawed analytic decisions. The PDoH study dropped from their analysis 5.4% of cancer cases with addresses in their study area rather than assign them proportionately to the possible sub-areas where they might have resided. Studies by Boice et al. also dropped cancer cases; additionally they failed to separate Apollo from Parks-area MCDs, failed to consider the possibility that cancer cases with addresses outside the Apollo-Parks area had residences within the area, and used population estimates that were too large to estimate expected cases. These analytic decisions resulted in masking excess cancer incidence in the Apollo MCDs. Additionally, in their discussion of results, prior investigators did not adequately discuss the limitations of spatial analyses for investigating the chronic effects of local pollution sources on cancer incidence.

38) According to official records, the age, race and sex adjusted SIR for all cancers in the MCDs surrounding the Apollo facility between 1990 and 2004 is 1.64 (95%CI 1.56 – 1.71). A statistically significant excess cancer incidence in the Apollo area remains even after removing cancer cases using the flawed method of Boice et al. This elevated SIR is particularly noteworthy because the measurement and classification problems discussed above are known to compromise the ability of epidemiological studies to detect effects of environmental pollutants.

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The opinions expressed in this report have been made to a reasonable degree of scientific certainty.

Steve Wing
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