

Plausibility of the Results from the Southeastern
Massachusetts Health Study

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Epidemiology Resources Inc.

826 Boylston Street, Chestnut Hill, Massachusetts 02167
617-734-9100 Fax 617-277-0335

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Prepared by:

Charles Poole, MPH, ScD

Submitted to:

**Boston Edison Company
800 Boylston Street
Boston, MA 02199**

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Summary

The Southeastern Massachusetts Health Study (Morris and Knorr 1990) is a case-control study of leukemia in relation to a measure of "potential for exposure to radioactivity" from the Pilgrim nuclear power plant. The study was conducted by the Massachusetts Department of Public Health (MDPH) in 22 towns located within 20 miles of the Pilgrim plant. The study suggests that at least 54 leukemias diagnosed from 1978 through 1983 were attributable to radioactive emissions from the plant. This result is scientifically implausible.

The 54 ostensibly attributable leukemias constitute two-thirds of all cases diagnosed in the study area over the six-year period. Thus, the total number of cases that occurred in the population should have been about three times higher than normal levels, given the population's composition by age, race and gender. To the contrary, the observed number of cases -- 79 in all or an average of 13.2 leukemias per year -- was slightly lower than normal, compared with any of 10 different areas in the United States in which cancer incidence is monitored routinely. The unremarkable leukemia rate in the 22-town area in Southeastern Massachusetts is incompatible with the suggestion from the MDPH study that two-thirds of the area's cases were due to radiation from the Pilgrim power plant.

The occurrence of 54 excess leukemia cases should have been detected, albeit as lower relative risks, in two independent analyses of leukemia death rates in Plymouth County, within which the entire MDPH study area is located. Both analyses show that Plymouth County residents experienced fewer leukemia deaths than expected in the years in which the 54 cases ostensibly occurred, 1978-1983.

The association in the MDPH study between leukemia and "potential exposure" to radiation from the Pilgrim plant abruptly disappeared after 1983, only 11 years from the date of plant start-up. This result is starkly inconsistent with the time course of increased leukemia risks observed in the most important epidemiologic studies on leukemia and ionizing radiation. Among the Japanese atomic bomb survivors and British patients receiving X-ray therapy for ankylosing spondylitis, elevated leukemia rates have persisted for more than three decades.

Finally, the results of the MDPH case-control study are irreconcilable with all major predictions of leukemia risk from low doses of ionizing radiation. Three well-known assessments (BEIR-V 1990, Shimizu et al. 1988, and Gofman 1990) yield a range of 350,000 to 750,000 person-rem as the population dose that would be required to produce 54 leukemias. In contrast, the estimated population dose to the study area resulting specifically from Pilgrim plant emissions amounted to less than 200 person-rem over the time period considered by the MDPH investigators. According to the

three risk assessments, this dose was 30 to 100 times lower than would be necessary to cause even one leukemia and several thousand times lower than the dose required to produce 54 leukemias.

The three risk assessments indicate that the background dose rate of penetrating whole-body ionizing radiation of about 80 millirem per person per year from sources other than radon is responsible for an average of one to three leukemias per year in the 22 towns. The dose-response model implied by the MDPH study predicts that radiation from background sources (such as cosmic rays from outer space) should be producing thousands of leukemias per year in the same population, in which an average of only 13 cases per year were actually identified.

In light of the extreme implausibility of the results of the MDPH study, a causal interpretation of those results is unwarranted. It is much more reasonable to suspect that the results were produced by one or more methodologic flaws. A review is in progress to determine the possible influence on the results of the procedures used to define the study population, to identify the leukemia cases, to select the controls, to assess ionizing radiation exposure, and to analyze the study data.

Introduction

In October 1990, the Massachusetts Department of Public Health (MDPH) released the final report of the Southeastern Massachusetts Health Study (Morris and Knorr 1990), a case-control study of leukemia in 22 towns located within 20 miles of the Pilgrim nuclear power plant. The study reports a strong association between leukemia and a "potential exposure score" that is intended to classify individuals with respect to exposure to ionizing radiation from the Pilgrim plant.

The Boston Edison Company asked Epidemiology Resources Inc. (ERI) to review the final report of the study. ERI had previously commented on the protocol (Poole et al. 1987), also at the request of Boston Edison. In a preliminary review of the final report (Poole et al. 1990), ERI briefly noted the apparent implausibility of the study's results and identified several methodologic aspects of the study that merit careful scrutiny.

The purpose of the present report is to assess in detail the MDPH study's "plausibility," by which is meant the degree of consistency between its results and major features of the existing scientific literature on ionizing radiation and leukemia. A thorough evaluation of the research methods is underway and will be presented upon completion.

Ostensibly Attributable Leukemia Cases

Leukemia was associated with "potential exposure to Pilgrim emissions" in the MDPH study only during the first two of the three time periods the investigators examined: 1978-1981 and 1982-1983. In each of these intervals, high relative risks were reported for both the "medium" and "high" potential exposure categories (Table 1). The study was restricted to leukemias other than chronic lymphocytic leukemia and to persons 13 years of age and older.

Each relative risk (RR) is an estimate of the ratio of the leukemia rate in the designated group to the rate in the reference, or "low" group. An RR of 1.00, which is assigned by convention to the reference group, means that the rate was neither increased nor decreased. An RR of 2.00 for a particular group would mean that the rate in that group was twice as high as in the reference group. Half of the cases in the group with the RR of 2.00 would have been produced by the exposure. The attributable proportion therefore would be 50 per cent. In general, the attributable proportion (AP) can be computed by the formula: $AP = (RR - 1)/RR$. When the $RR = 1.00$, the $AP = 0$.

Once the AP has been computed for a particular group, it can be multiplied by the number of cases in that group to yield the number of cases attributable to "potential exposure." The results are called "ostensibly" attributable cases in this report as a reminder that the computation is made under the hypothetical assumption that the data are valid and that they therefore represent a causal association.

Table 1
Ostensibly Attributable Leukemia Cases in the 22-Town Area

Years	Potential exposure group	Relative risk	Attributable proportion	Number of cases	
				Total	Attributable
1978-1981	Low	1.00	0%	8	0
	Medium	5.14	81%	22	18
	High	3.74	73%	8	6
1982-1983	Low	1.00	0%	2	0
	Medium	3.10	68%	13	9
	High	15.70	94%	16	15
1978-1983	All cases interviewed	NA	68%	69	47
	All cases identified	NA	68%	79	54

Source: Morris and Knorr (1990), Tables 32 and 33.
Abbreviation: NA, not applicable.

As shown in Table 1, with the numbers of ostensibly attributable cases rounded to the nearest whole number, the MDPH study suggests that 47 of the 69 leukemia cases for whom interviews were obtained were caused by Pilgrim emissions. Interview information was unavailable for 10 cases (Morris and Knorr 1990, page 52), all of whom were diagnosed in the years 1978-1983 (Morris and Knorr, personal communication). In the last row of Table 1, therefore, the AP of 68 per cent is multiplied by the total of 79 cases to yield 54 ostensibly attributable cases.

The MDPH study thus suggests that about two-thirds of the cases diagnosed in the 22-town area over the six years from 1978 to 1983 would not have occurred in the absence of radioactive emissions from Pilgrim. As a consequence, the observed number of 79 cases in the study population -- an average of 13.2 per year -- should have been about three times higher than usual for such a population, given its size and composition by age, race and gender. This distribution is shown in Table 2.

Table 2
1980 Population of the 22-Town Study Area by Age, Race and Gender

Age (years)	White males	Nonwhite males	White females	Nonwhite females	Total
13 - 14	5,144	403	4,906	442	10,895
15 - 19	12,191	438	11,551	393	24,573
20 - 24	8,449	328	9,339	293	18,409
25 - 29	9,423	334	10,433	297	20,487
30 - 34	11,185	290	11,927	281	23,683
35 - 39	9,644	276	9,734	264	19,918
40 - 44	6,709	204	6,665	179	13,757
45 - 49	6,088	174	5,808	175	12,245
50 - 54	5,675	195	5,785	212	11,867
55 - 59	5,319	193	5,918	190	11,620
60 - 64	4,674	149	5,258	166	10,247
65 - 69	3,946	105	4,826	118	8,995
70 - 74	2,778	84	3,938	77	6,877
75 - 79	1,766	44	2,867	54	4,731
80 - 84	952	42	2,017	36	3,047
≥ 85	660	37	1,819	31	2,547
Total	94,603	3,296	102,791	3,208	203,898

Source: U.S. Census data provided by the Massachusetts Institute for Social and Economic Research.

Expected Cases in the Study Area, 1978-1983

"Expected" leukemia cases are computed by multiplying the leukemia rates in a comparison population by the person-time of observation in the population under study, within categories of age, race and gender. The results are then summed over all the categories to produce a single number of expected cases. The expected number, therefore, is the number of cases that would have occurred in the study population if it had experienced the category-specific leukemia rates that actually did occur in the comparison population.

Ten separate comparison populations were selected for this analysis to provide a perspective on the range of leukemia rates experienced in different parts of the United States. One comparison population is Massachusetts as a whole, with data provided by the Massachusetts Cancer Registry for the years 1982-1983. (Data for 1978-1981 are unavailable because 1982 was the Registry's first year of operation.) The remaining comparison populations are the nine cancer registry areas in the National Cancer Institute's Surveillance, Epidemiology and End-Results (SEER) program. They are the metropolitan areas of Atlanta, Detroit, San Francisco-Oakland, and Seattle-Puget Sound and the states of Connecticut, Hawaii, Iowa, New Mexico and Utah.

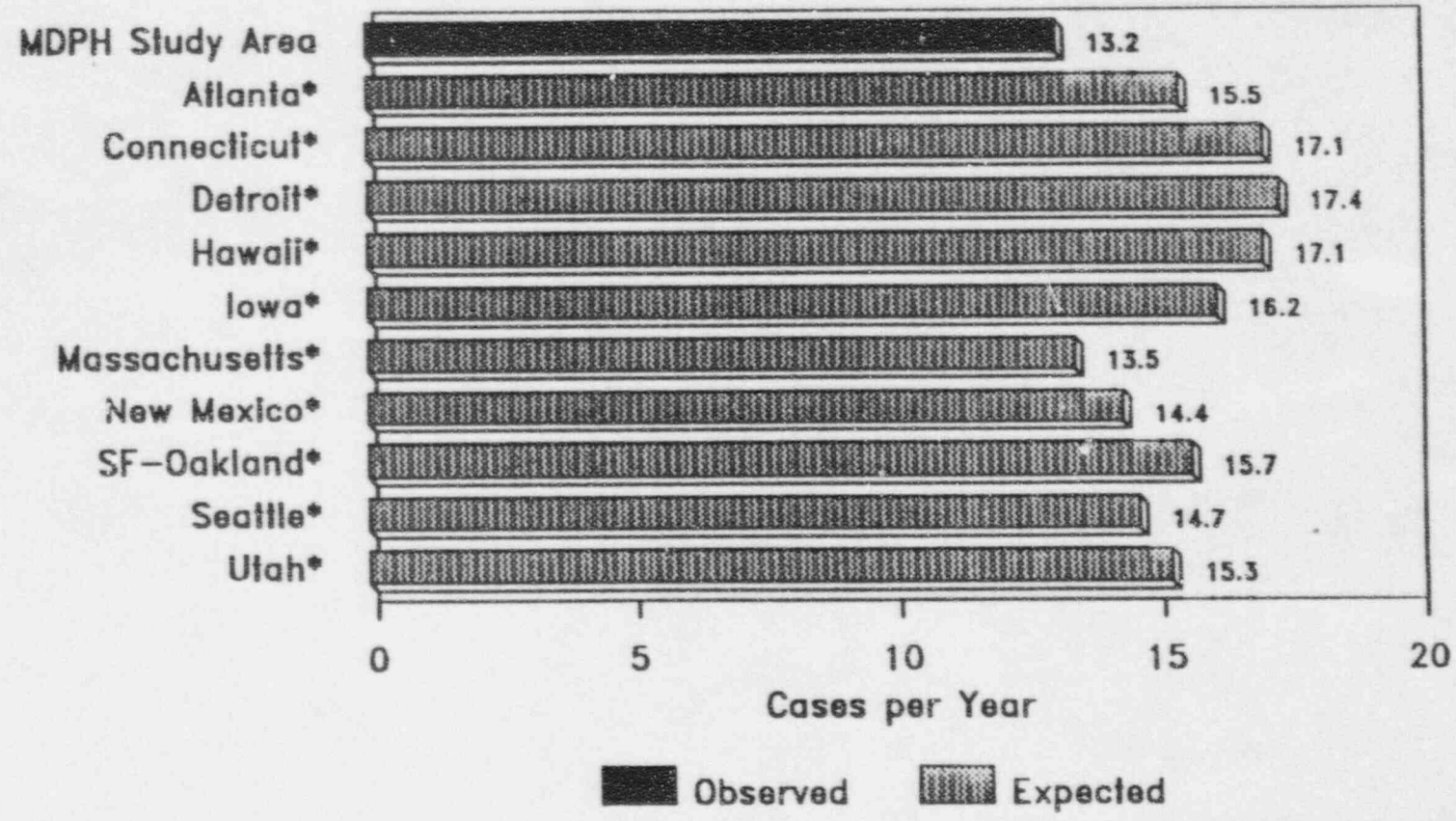
Leukemia data for these populations for the years 1978-1983 were obtained from the SEER program. For consistency with the MDPH study, all computations excluded chronic lymphocytic leukemia, which is widely considered to be unrelated to ionizing radiation.

Figure 1 contrasts the observed number of 13.2 cases per year in the MDPH study area with the expected numbers based on the 10 comparison populations. Variability among the expected comparisons is minimal, with a range from 13.5 per year using Massachusetts rates to 17.4 per year using rates from the Detroit metropolitan area. The leukemia rate in the MDPH study area is virtually identical to the rate in Massachusetts as a whole and slightly lower than rates elsewhere in the United States. The threefold excess suggested by the MDPH study for the 22-town area is not remotely evident.

Leukemia Mortality Rates in Plymouth County

Two analyses have been reported of leukemia mortality rates (i.e., rates of death from leukemia) in Plymouth County, the county in which the Pilgrim plant is located. One analysis compared leukemia mortality rates between Plymouth County and the remainder of Massachusetts over the years 1969-1986 (Poole et al. 1988). The other analysis compared Plymouth County with the United States over a longer time period: 1950-1984 (Jablon et al. 1990). The results of both analyses, shown in Table

Figure 1
Observed and Expected Leukemias
in the MDPH Study Area, 1978-1983



*Comparison areas used to compute expected cases in the MDPH study area controlling age, race and gender.

3. indicate that the leukemia death rates in Plymouth County were somewhat lower than expected, both before and after the Pilgrim plant began operating in December, 1972.

Table 3
Results of Analyses of Leukemia Mortality in Plymouth County

Comparison area	Years	Relation to date of Pilgrim plant start-up	Relative risk
Massachusetts ^a	1969-1972	Before	0.99
	1973-1976	After	0.88
	1977-1980	After	0.84
	1981-1986	After	0.84
United States ^b	1950-1952	Before	0.90
	1953-1957	Before	0.91
	1958-1962	Before	0.89
	1963-1967	Before	0.93
	1968-1972	Before	0.82
	1973-1977	After	0.81
	1978-1982	After	0.81
	1983-1984	After	0.87

^a Source: Poole et al. (1988)

^b Source: Jablon et al. (1990)

The last two time intervals in each of the mortality analyses, 1977-1986 (Poole et al. 1988) and 1978-1984 (Jablon et al. 1990), are the relevant time periods for comparison with the years 1978-1983, during which the MDPH study results suggest that the 54 attributable leukemias occurred. Poole et al. reported 207 leukemia deaths (excluding chronic lymphocytic leukemia) in Plymouth County during the period 1977-1986; Jablon et al. reported 163 leukemia deaths (all leukemia types) in the county during the period 1978-1984. If 54 deaths in each analysis were attributable to Pilgrim plant emissions, the expected numbers of leukemia deaths would have been about

$207 - 54 = 153$ in the analysis by Poole et al. and $163 - 54 = 109$ in the analysis by Jablon et al. The corresponding relative risks (i.e., the observed leukemia deaths divided by the expected leukemia deaths) would have been $207 \div 153 = 1.4$ in the analysis by Poole et al. and $163 \div 109 = 1.5$ in the analysis by Jablon et al.

The anticipated relative risks of 1.4 and 1.5 are considerably lower than the relative risks reported in the MDPH study, all of which were greater than 3.0 (Table 1), even though all the analyses ostensibly should be reflecting the same 54 excess leukemias. The reasons for the disparity are features of the mortality analyses that would tend to "dilute" their ability to reflect the MDPH study results. The most important diluting factor would be the focus on Plymouth County in the mortality analyses in contrast to the focus on a portion of Plymouth County -- the 22-town study area -- in the MDPH study. In 1980, the 260,336 residents of all ages of the MDPH study area constituted only 64 per cent of the county's total population of 405,392 persons. An absolute excess of 54 leukemia cases or deaths would thus correspond to lower relative risks in the county-level mortality analyses. The same 54 leukemias would constitute a smaller proportion of the total number of leukemia deaths in the county than of the total number of leukemia cases in the smaller MDPH study area.

Less important sources of dilution would include the lack of perfect correspondence among the time periods considered in the three analyses and the inclusion of chronic lymphocytic leukemia in the analysis by Jablon et al. but not in either of the other two analyses. The distinction between leukemia incidence and leukemia mortality also should have been relatively unimportant because, among adults, the average leukemia survival period (i.e., the average time from diagnosis to death) is less than one year (Axtell et al. 1976).

The actual estimates in the two mortality analyses were 246 expected leukemia deaths, based on Massachusetts rates, for the years 1977-1986 in the analysis by Poole et al. (1988) and 197 expected leukemia deaths, based on United States rates, for the years 1978-1984 in the analysis by Jablon et al. (1990). Thus, the relative risks in the two analyses were virtually identical: $207 \div 246 = 0.84$ (Poole et al.) and $163 \div 197 = 0.83$ (Jablon et al.). Ninety-five per cent confidence intervals for these relative risk estimates are: 0.73 to 0.96 (Poole et al.) and 0.71 to 0.96 (Jablon et al.). Consequently, the favorable leukemia mortality experience suggested by both analyses for Plymouth County is inconsistent with the relative risks of 1.4 to 1.5 that the results of the MDPH study would lead one to expect those analyses to produce.

Time Course of Elevated Leukemia Risk Following Radiation Exposure

In contrast to the high relative risks in the first two time periods of the MDPH case-control study (Table 1), the association between leukemia and "potential exposure" to Pilgrim plant emissions completely disappeared in the third time period, 1984-1986. In these three years, the relative risks were 0.59 for the medium potential exposure category and 0.87 for the high category (Morris and Knorr 1990, Table 34). Because the three time periods contained approximately equal numbers of subjects (e.g., 38, 31 and 36 cases, respectively), the results for the third time period were no less statistically precise than the results for either of the two earlier intervals. There is consequently no reason to disagree with the MDPH's description of the disappearance of the association in the third time period as a "major finding" of the study (Morris and Knorr 1990, page iii; MDPH 1990, page 2).

The midpoints of the three time periods in the MDPH study are the end of December, 1979 (for the period 1978-1981), the end of December, 1982 (for the period 1982-1983) and the end of June, 1984 (for the period 1984-1986). These midpoints correspond to intervals of seven, 10 and 12.5 years after the Pilgrim plant started operating in December, 1972.

As shown in Figures 2 and 3, the disappearance of the association in the third time period is extremely inconsistent with the two key studies in the extensive existing literature on leukemia in relation to ionizing radiation: the ongoing studies of Japanese atomic bomb survivors (Figure 2, Shimizu et al. 1988) and of British ankylosing spondylitis patients treated with high doses of x-rays (Figure 3, Darby et al. 1987). In each of these studies, increased leukemia risk has been observed to persist for at least 30 years after initial exposure. (The relative risks in Figures 2 and 3 are plotted on logarithmic scales at the recommendation of Gladen and Rogan (1983) to account for the asymmetry of the relative-risk scale, on which inverse associations are represented by values of zero to one and direct associations by values of one to infinity. See also Morgenstern and Greenland (1990).)

The fact that the atomic bomb and ankylosing spondylitis studies measured leukemia mortality as opposed to leukemia incidence introduces a negligible bias into the contrasts in Figures 2 and 3 because, as previously noted, the average survival time for adult leukemia patients is less than one year (Axtell et al. 1976). The disappearance of the association in the MDPH study after a maximum of 11 years from Pilgrim plant start-up is another indication of the implausibility of the study's results.

Figure 2
Leukemia by Time Since First Exposure
A-Bomb and MDPH Studies

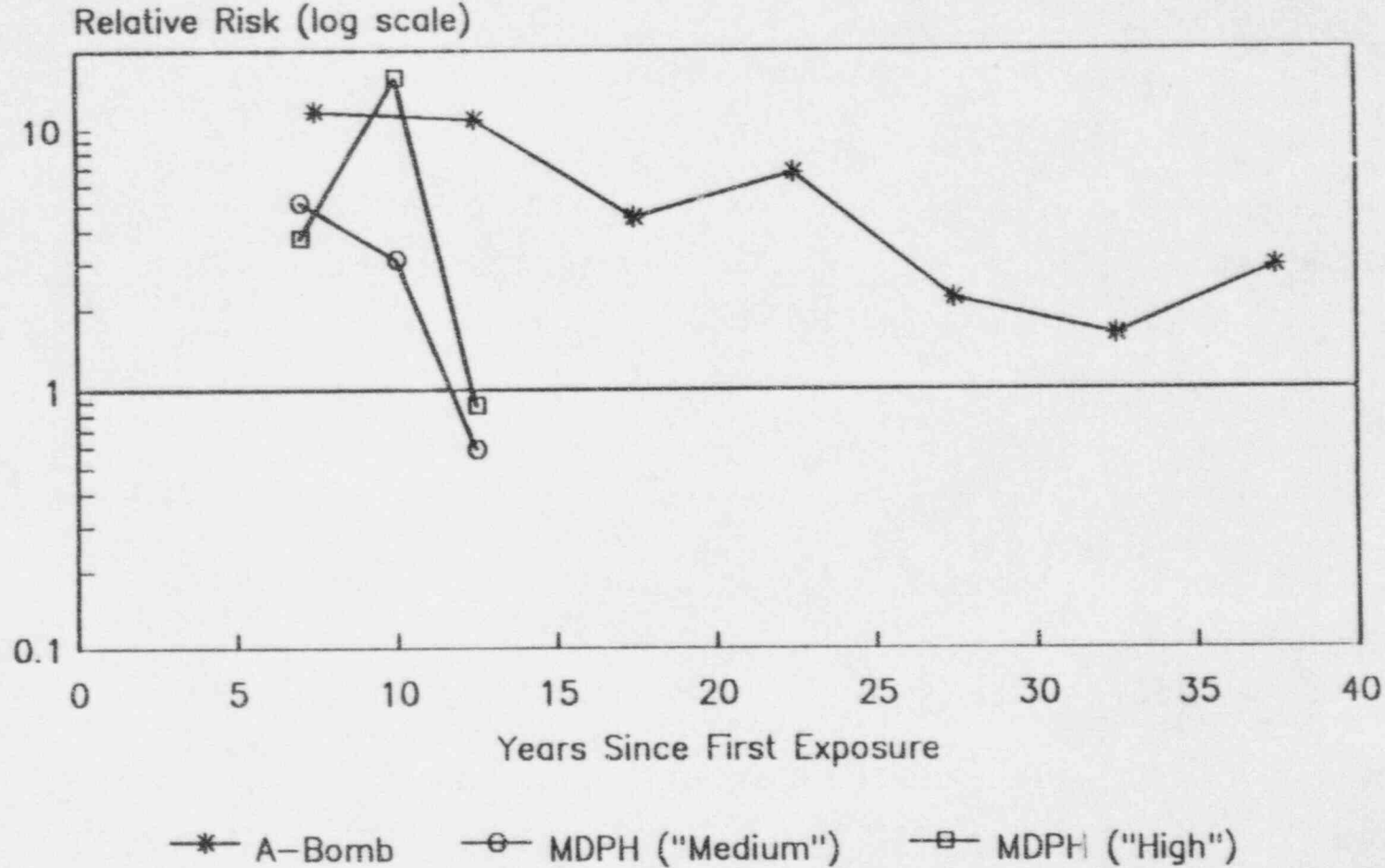
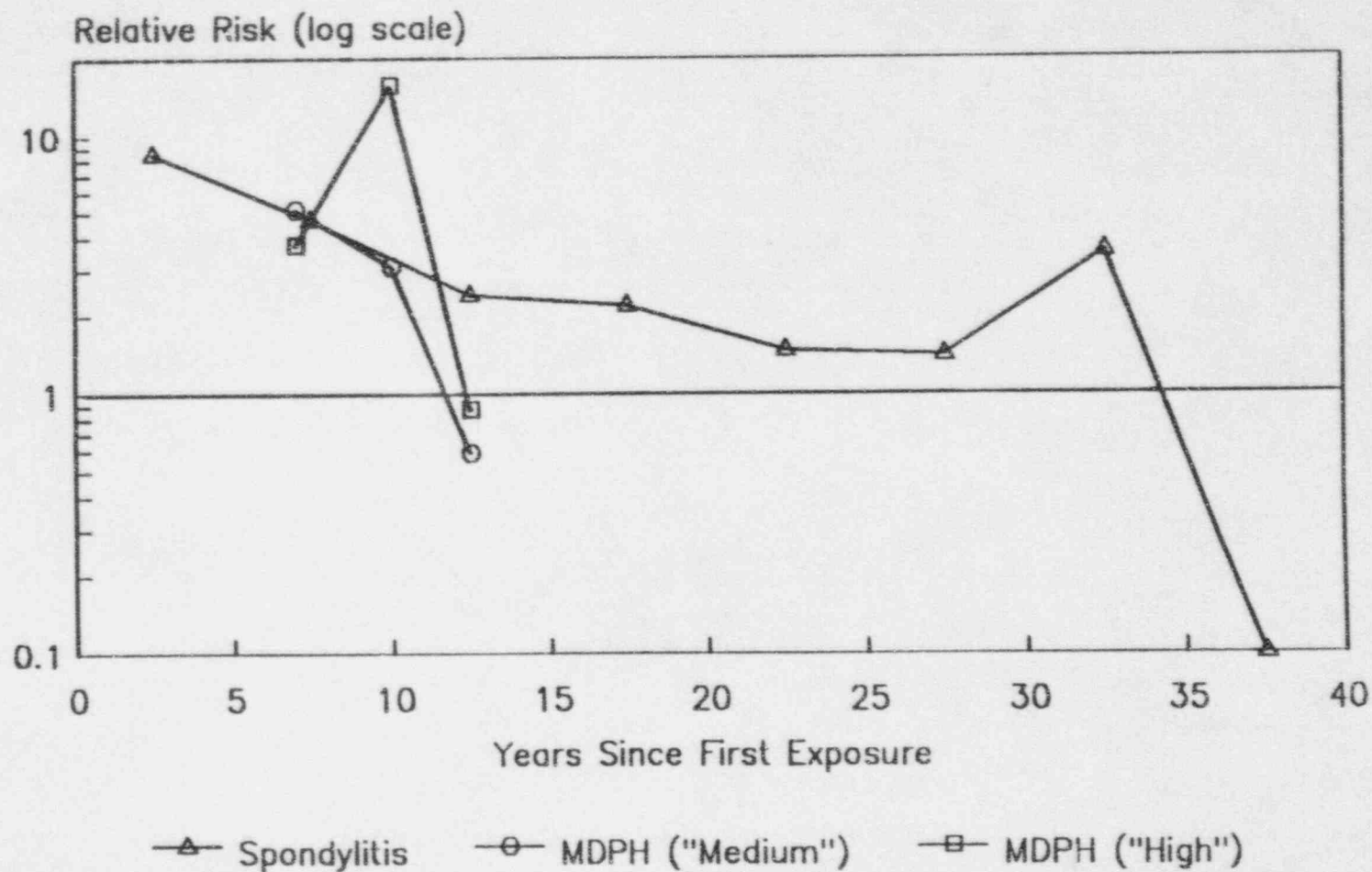


Figure 3
Leukemia by Time Since First Exposure
Ankylosing Spondylitis and MDPH Studies



Predictions of Leukemia Risk From Low Radiation Doses

Several authorities have produced risk assessment models to predict the degree of increased leukemia risk from exposures to ionizing radiation at low doses and low dose rates. The models make use of different assumptions and interpretations of the available data, especially the previously mentioned studies of atomic bomb survivors and ankylosing spondylitis patients.

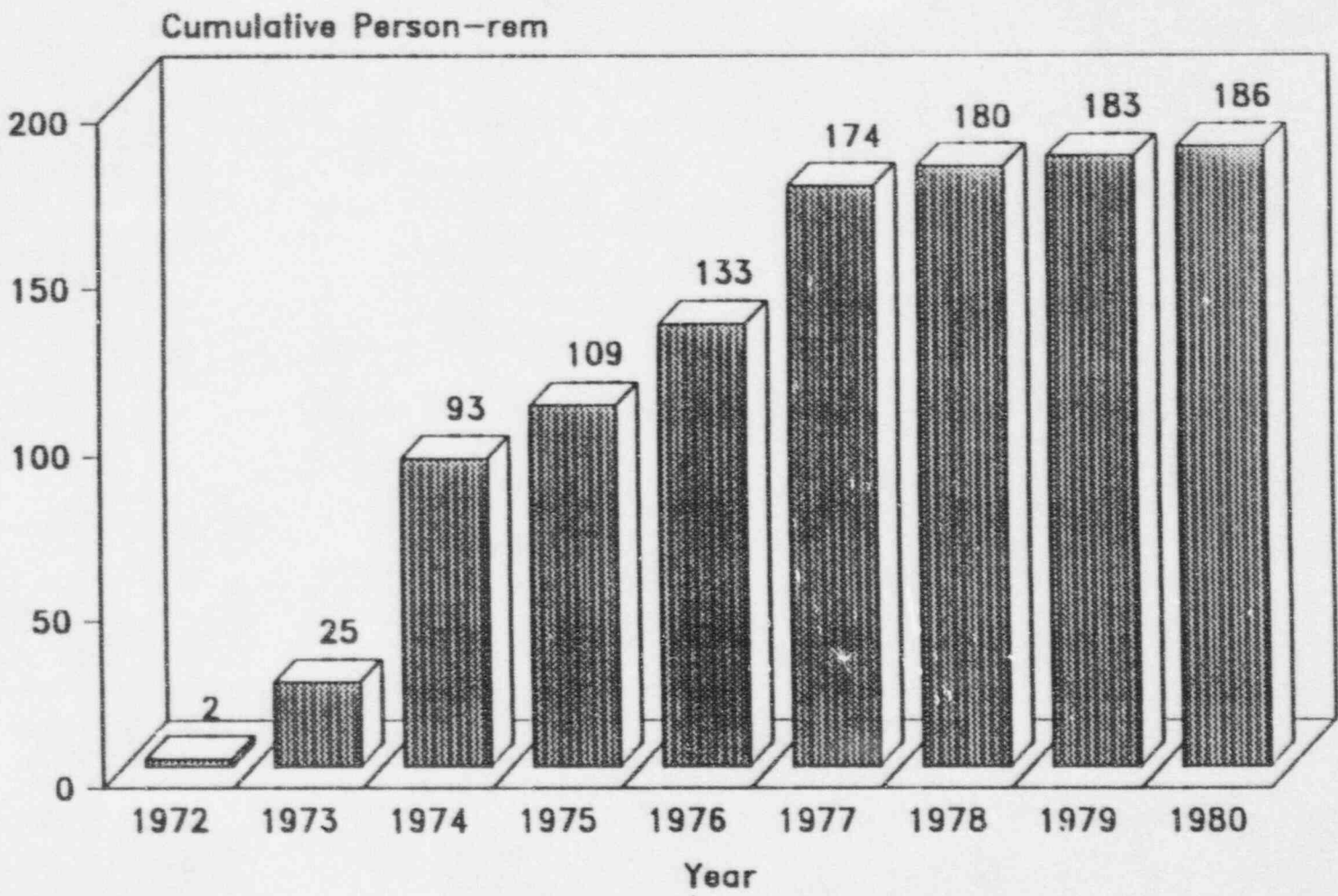
Three of the best known risk assessments of leukemia and low-dose ionizing radiation are those recently offered by the Fifth National Research Council Committee on the Biological Effects of Ionizing Radiations (BEIR-V 1990), the Radiation Effects Research Foundation (RERF) (Shimizu et al. 1988), and the Committee for Nuclear Responsibility, Inc. (CNR) (Gofman 1990).

A comparison between the three risk assessments and the results of the MDPH case-control study requires an estimate of the population dose from Pilgrim plant emissions over the pertinent time period. The potential exposure scores in the MDPH study were computed with an assumption of a five-year minimum "latency period" (Morris and Knorr 1990, pages ii, 42-45, 63-65). The implication of this assumption is that ionizing radiation exposure has no effect at all on leukemia risk within the first five years. As shown in Figure 3, this assumption is inconsistent with the results of the study of ankylosing spondylitis patients, in which elevated leukemia risk was observed in the first five-year interval (Darby et al. 1987). The study of atomic bomb survivors has no relevant information, because follow-up did not begin until five years after the bombs were detonated (Shimizu et al. 1988).

Procedurally, the assumption of a five-year minimum "latency period" means that, in the MDPH study, "...any residence or job held during the five years prior to diagnosis was not counted in estimating an individual's exposure potential" (Morris and Knorr 1990, page ii). The last year for which the MDPH study reported an association was 1983 (Table 1). Consequently, according to the study's exposure model, the ostensible increases in risk were due to exposures sustained between 1972 and 1978.

Cumulative population dose estimates, by year from 1972 to 1980, are shown in Figure 4 for the entire population residing within 20 miles of the Pilgrim plant. The estimates were produced by the Yankee Atomic Electric Company with standard dosimetry methods and using data that were collected and reported in each year of the study period. The dose estimates include not only the 22 towns in the MDPH study area, but also several towns on Cape Cod that lie within 20 miles of the plant but were not included in the study. Through 1978, the estimates indicate a population dose of 180 person-rem specifically from Pilgrim plant emissions. Because abnormal radiation releases in 1974 and 1977 dominate the cumulative dose through the present date, the results of the computations below would not be changed materially if

Figure 4
Cumulative Radiation Dose from Pilgrim
Emissions, MDPH Study Area, 1972-1980



Source: Yankee Atomic Electric Company

the cumulative dose through a later date than 1978 (e.g., 1980 or 1983) were to be used.

The starting point for the computation is the population dose that each of the three risk assessments predicts would be necessary to produce one leukemia. These doses, ranging from 6,500 to 13,900 person-rem (rounded to the nearest hundred person-rem), are shown in the first column of Table 4. The population doses required to produce the 54 ostensibly attributable leukemias estimated by the MDPH study (Table 1) are obtained simply by multiplying the figures in the first column of Table 4 by 54. By dividing the figures in the second column (which are rounded to the nearest thousand person-rem) by the 180 person-rem estimated for the 20-mile population (Figure 4), one can obtain "implausibility factors," or approximate indications of the degree to which the MDPH results are inconsistent with the three risk assessments. These factors (rounded to the nearest thousand) range from 2,000 to 4,000. Thus, the MDPH results differ by at least three orders of magnitude from the predictions of the three low-dose models.

Table 4
Predicted Lifetime Leukemia Risks from Low Doses of Ionizing Radiation

Source	Person-rem required to produce:		Leukemias produced by 180 person-rem ^a
	One leukemia ^a	54 leukemias ^a	
RERF ^b	13,900	751,000	0.01
BEIR V ^c	10,500	567,000	0.02
CNR ^d	6,500	351,000	0.03

^a For a single, whole-body exposure and lifetime follow-up.

^b Shimizu et al. (1988), Table 19, leukemia deaths, LQ model, 0-2 Gy dose range, mean of male and female predictions.

^c BEIR-V (1990), Table 4-2, 0.1 Sv panel, leukemia deaths, mean of male and female predictions.

^d Gofman (1990), pp. 24-5, 36-19, leukemia cases.

Abbreviations: RERF, Radiation Effects Research Foundation; BEIR-V, Fifth National Research Council Committee on the Biological Effects of Ionizing Radiations; CNR, Committee for Nuclear Responsibility, Inc.

To add perspective, the final column of Table 4 gives the number of leukemias that each risk assessment predicts would be produced by a dose of 180 person-rem. The predictions range from one one-hundredth to three one-hundredths of a leukemia. In

other words, according to the three risk assessment models, the Pilgrim plant has not released nearly enough ionizing radiation to cause even one leukemia.

Three features of the foregoing computations cause them to understate the degree of inconsistency between the MDPH study results and the predictions from the three risk assessments. First, the 54 attributable leukemias derived from the MDPH study cannot include any cases that were ostensibly caused by radiation from the Pilgrim plant but that were diagnosed after the exposed residents moved away from the study area. Second, whereas the three risk assessments in Table 4 are attempts to predict lifetime leukemia risks, the 54 ostensibly attributable leukemias in the MDPH study occurred in only a six-year period. Third, although the computation of necessity assumes that no leukemia cases in the "low" potential exposure group were due to Pilgrim plant emissions, the MDPH study's dose-response model implies that attributable cases did in fact occur in this group. In essence, the 54 attributable leukemias in the "medium" and "high" groups represent only the cases that ostensibly would not have occurred had those two groups received a "low" degree of "potential exposure." Since the study assigned nonzero potential exposure scores to the persons in the "low" group, the study implies that "low" potential exposure does confer some degree of increased risk.

Implications of the MDPH Study for Leukemia Risk from Background Radiation

The "background" dose of ionizing radiation from environmental sources other than radon varies to some degree, but seldom differs appreciably from an average of approximately 80 millirem per person per year of penetrating whole-body radiation (NCRP 1987). Over the seven years from 1972 to 1978, therefore, the population of approximately 260,000 residents of all ages of the MDPH study area received a cumulative background dose of about 146,000 person-rem.

As previously noted, the MDPH study suggests that a population dose of about 180 person-rem sustained over the same seven-year period specifically from Pilgrim plant emissions was able to cause at least 54 leukemias over the six years from 1978 to 1983. Thus, if the study results were valid, the background dose would have caused

$$(54 \text{ leukemias}) \times (146,000 \text{ person-rem} / 180 \text{ person-rem}) = 43,800 \text{ leukemias,}$$

or about 7,000 leukemias per year in the population of these 22 towns during the same six-year interval. This implication is clearly ludicrous, given the average number of 13.2 leukemias that the MDPH investigators actually observed in the study population over the same period of time (Table 1).

Possible Explanations for the MDPH Study Results

The preliminary ERI review of the final report of the MDPH study identified several areas of methodologic concern (Poole et al. 1990). These areas include the fashion in which the study population was defined, the way in which leukemia cases were identified, the procedures used to select controls, and the manner in which "potential exposure" to Pilgrim plant emissions was estimated. Each of these features of study design and conduct, as well as others, may have contributed to the study's implausible findings. A detailed review of the study's methods and materials is underway.

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