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**A Survey of Studies of Occupational Populations
Exposed to Low-Level Radiation**

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A SURVEY OF STUDIES OF OCCUPATIONAL POPULATIONS
EXPOSED TO LOW-LEVEL RADIATION

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Some occupational exposures to low and, in some cases, higher levels of radiation in populations large enough for epidemiologic study occurred early, before the hazards of such exposure were fully recognized. In other later cases, the need for protection was recognized but the exposure of workers occurred under conditions that were not favorable for the measurement of doses to individual employees. Finally, worker populations have been exposed in facilities where the nature of the exposure and the personnel protection systems permitted reasonably accurate dose estimation. Studies of these various types of occupational populations and exposures are in progress and will be reported here in a roughly historical sequence.

RADIUM DIAL PAINTERS

Two populations of workers have incurred deposition of radium-226 and radium-228 of sufficient magnitude to warrant their study - radium dial painters, who were employed between 1912 and 1930, and chemists. The study to date has been conducted by the Center for Human Radiobiology at Argonne National Laboratory on the former group of 1750 female dial painters, the larger and more accessible of the two groups. Many of the dial painters ingested relatively large quantities of radium by moistening the tips of their brushes with their lips. Early case finding was based on availability of study material, introducing a potential bias related to outcome. More

recently, follow-up of cohorts generated from employment rosters and other company records has been undertaken. In pursuing the study of cohorts, the investigators have attempted to minimize any bias due to past selection procedures. In the course of these studies, many excess cases of bone sarcoma, due to radium deposition in bone, and of cancer of the paranasal sinuses and mastoid air cells, possibly due to both radium deposition and radon gas, have been identified. (1) Dosimetry is based on the analysis of radium deposition in body tissues, most of which were obtained by exhumation, or on in vivo estimation from radon exhalation measurements. Results of the studies have provided a basis for setting occupational exposure limits for radium and, in a supportive role, for other bone-seeking radionuclides. The exposures studied to date do not strictly qualify as 'low-level, but the importance of the studies warrants their inclusion in this report.

MEDICAL RADIOLOGISTS

Medical radiologists are an occupational group that was heavily exposed to radiation before full awareness of the risks associated with such exposure. Since then, radiologists have improved their protection practices, and x-ray equipment has been increasingly designed to control personnel exposure, resulting in less exposure of the radiologists. A study of the mortality rates of radiologists compared with members of other specialties has been conducted by Johns Hopkins University during the past two decades. The specialties selected for comparison were internal medicine, ophthalmology, otolaryngology, pathology and orthopedic surgery. Dosimetry data were not available, but

the populations were divided into cohorts according to the period of entry into specialty practice, i.e., 1920-1929, 1930-1939, etc. This grouping of the study population provided a qualitative grading of exposure. A report comparing mortality rates for the different specialties and cohorts indicated that radiologists experienced excess risk from all causes in all cohorts until 1940. Excess risk due to all cancers continued through the period of observation of the study. An excess risk of leukemia, aplastic anemia and skin cancer was observed by Matanoski, et al.⁽²⁾ in the 1920-1929 cohort, for leukemia and skin cancer but not aplastic anemia in the 1930-1939 cohort, and for none of these subsequently. Excess lymphoma and multiple myeloma were described in the 1930-1939 and 1940-1949 cohorts, but later data indicated that the myeloma excess may also be found in other medical specialists.⁽³⁾

The increased mortality due to causes other than cancer, which was attributed to a possible aging effect in the American radiologist study, has not been confirmed in studies of either Japanese survivors of the atomic bombings or British radiologists.

URANIUM MINERS

Several studies have been conducted on miners exposed to radon and its daughters, the source of radiation exposure of uranium miners. Mining of minerals other than uranium, such as iron, zinc and lead, may involve significant exposure to radon and its daughters. The epidemiologic studies have included populations of such miners as well as uranium miners. The studies of the health effects of exposure to radon and its daughters have been carried

out in Canada, Czechoslovakia, Sweden and the United States and have identified an excess of lung cancer in the miners.⁽⁴⁾ Risk estimates have been developed on the basis of those studies but are usually stated with reservations that reflect inadequacies in the dosimetry. To date, personnel dosimeters for radon and daughter exposure have not been developed sufficiently to permit their widespread use. The dose estimates for the subjects of these various studies are based on air concentrations and, for the most part, did not reflect the work places of individual miners. Thus, they have necessarily been crude approximations, especially for the earlier periods of higher exposure before more stringent personnel protection practices were instituted. These factors tend to reduce confidence in the dose-response relationships upon which risk estimates for lung cancer in the miners are based. The same caveats apply to risk estimates of lung cancer in the general population due to exposure to radon and its daughters in houses because they are based on the risk estimates for miners.

THORIUM WORKERS

Another study of an internal emitter by the Argonne Center of Human Radiobiology is that of thorium deposition in former employees of a plant operated from the early 1930s until 1973 by a thorium processing company. Of a total of 4789 employees, 548 deaths have been identified through Social Security Administration (SSA) ascertainment. A group of 558 men who worked for one year or longer in job classifications involving probable exposure to thorium compounds are included in a morbidity study. Dosimetry is based on in vivo gamma counting of Bi-212 in the body and measurements of thoron

in exhaled air. The exposure of workers to external radiation and the ambient levels of radioactivity are estimated to have been within current permissible levels. The study is in a preliminary stage, and results are not available yet.

MILITARY TEST PERSONNEL

Exposures of military personnel occurred during a number of nuclear tests in Nevada and in the Pacific. An epidemiologic study of military personnel involved in certain of those tests has been authorized and will be conducted by the Medical Follow-up Agency of the National Research Council. A tentative decision has been reached to follow up participants in four series of tests. Dosimetry data, based on film badge readings, will be provided to the investigators by the Defense Nuclear Agency of the Department of Defense. The vast majority of exposures were within permissible limits.

A preliminary investigation revealed that inhalation or ingestion of radio-nuclides was not a major hazard at the one shot (Smoky) investigated thus far. Mortality will be investigated, and morbidity studies are under consideration. The roster of subjects to be included in the study is scheduled to be completed in the fall of 1980.

DOE-CONTRACTOR FACILITIES

The principal studies of workers with well documented exposure histories have concerned employees of certain U.S. Department of Energy (DOE) contractor facilities and, also, naval shipyards. Similar studies are now under way in other countries but were started more recently and, as a result, are less

advanced now. This discussion is limited to the studies of DOE-contractor employees including workers at the Hanford site, the Oak Ridge plant and those potentially exposed to plutonium at several plants, notably at Rocky Flats and Los Alamos.

The investigations of the health of workers at the Hanford and Oak Ridge plants stem from studies included initially in the AEC-sponsored Health and Mortality Study (principal investigator, Thomas F. Mancuso), which was conducted from 1964 to 1977. Most of the data collection for those studies occurred during that period but has been continued subsequently. Since September 1977 the study of Oak Ridge workers has been carried out by Oak Ridge Associated Universities in Oak Ridge and of Hanford workers by staffs of the Hanford Environmental Health Foundation and Pacific Northwest Laboratory in Richland. In addition, the Hanford data have been analyzed during the past few years by Dr. Mancuso and his associates, Alice Stewart and George W. Kneale, and by a team consisting of George B. Hutchison, Brian MacMahon, Seymour Jablon and Charles E. Land.

The Hanford plant has been in operation since 1944. Activities conducted at the plant have included fuel fabrication, reactor operation, chemical separation and purification of plutonium, waste management, and a diverse research program. The cumulative employee population is about 45,000 and the current population about 10,000. External radiation has been the most important source of exposure; only about 450 cases of verified internal exposure have been observed in the entire work experience. The cumulative population exposure through 1977 was 78,000 man-rem. Using internal controls

and analyzing for trend of mortality with increasing radiation exposure, Gilbert and Marks⁽⁵⁾ and Hutchison, MacMahon, Jablon and Land⁽⁶⁾ demonstrated a correlation between increasing levels of radiation exposure and mortality due to multiple myeloma based on a few high-exposure cases. A correlation between radiation exposure and cancer of the pancreas was demonstrated at levels of significance of 7%⁽⁵⁾ and 1%⁽⁶⁾. No correlation was established between radiation exposure and all cancer cases, cancer of the lung or myeloid leukemia in those analyses. Using a radically different approach to the analysis from that of either study, Mancuso, Stewart and Kneale⁽⁷⁾ demonstrated significant correlations between radiation exposure and multiple myeloma, cancer of the pancreas, cancer of the lung and all cancer. They further calculated the number of excess deaths due to cancer in the worker population and the doubling doses for all cancer, lung, bone marrow and pancreas. After additional deaths were analyzed, their doubling doses were revised to substantially higher values with substitution of the group of pancreas, stomach and large intestine for pancreas alone.⁽⁸⁾ The analyses by Mancuso, Stewart and Kneale have been criticized extensively.^(5,6,9,10,11)

Oak Ridge Associated Universities has analyzed or plans to analyze data on workers at the various Oak Ridge facilities and certain plants at which uranium was processed during earlier periods, such as those of the Mallinckrodt and National Lead Companies. Data files in various stages of completeness are currently available for the several facilities. An analysis of data for the period until the end of 1973 on workers at the Oak Ridge Y-12 plant has been completed by Polednak.⁽¹²⁾ The analysis has been conducted

separately for workers employed only at the Y-12 plant by the Tennessee-Eastman Corporation (TEC) from 1943-1947 and for workers employed only at the Y-12 plant by its successor contractor, Union Carbide Corporation, which has operated the plant from 1947 until now. The plant under TEC was engaged in the conversion of uranium oxide to chloride and in uranium enrichment by an electromagnetic separation process, which was then discontinued. Uranium dosimetry was poorly developed during the early period. Standardized mortality ratios (SMRs) relative to the U.S. population have been calculated for the white male worker population of about 19,000 for all cancers and for lung cancer. SMRs for specific cancer types were also calculated for a population of 4,008 white males employed for at least one year in selected departments involving uranium dust exposure. Workers at the Y-12 plant during the period of Union Carbide operation since 1947 have engaged in uranium processing and metal production. The total relevant population has consisted of 11,000 workers. The recent preliminary analyses were carried out on about 5,000 white males, who were first employed at the plant before 1970. Both external radiation dosimetry and urinary bioassay values are available for this population. Among 316 deaths, no statistically significant excesses of observed over expected deaths occurred for all causes, all cancer cases and various specific cancer types.⁽¹²⁾ Analyses are not yet available for correlation of exposure with mortality.

Since 1976, a study of plutonium workers in major DOE-contractor facilities has been under development. The study is conducted by the Los Alamos Scientific Laboratory (LASL). Data have been collected thus far for plutonium workers at

LASL; the Rocky Flats plant in Golden, Colorado; the Mound Laboratories in Miamisburg, Ohio; and the Savannah River plant, Aiken, South Carolina. The populations with plutonium burdens at the various plants include about 3,000 at Rocky Flats, 1,000 at Los Alamos, 400 at Mound Laboratories and 200 at Savannah River. An additional 200 such workers at Hanford and less than 100 at Oak Ridge have available data on file, which will be incorporated into the study at a later date. Studies of mortality and morbidity are planned. Personnel rosters of workers with plutonium burdens and their controls at the Rocky Flats, Los Alamos and Mound facilities have been submitted to Social Security Administration for ascertainment of deaths. However, death certificates are not yet available for the analysis of mortality in these populations. Morbidity and mortality data have been obtained for a limited number (224) of LASL workers with plutonium burdens ≥ 10 nCi. No apparent excess of cancer mortality has been observed in this small population.⁽¹³⁾ Meaningful analyses and results will await availability of mortality data for the larger populations from the several plants under study. An analysis of Rocky Flats data is projected for completion by the end of 1980.

Additional studies in early stages include a registry of all workers at DOE-contractor facilities who have received radiation doses greater than the allowable limit of 5 rem during any year since 1947. These data are collected by ORAU and will be analyzed by that organization. About 2,000 workers are expected to meet this criterion. Both mortality and morbidity studies are contemplated. Control groups will be generated when the study population has been developed.

SHIPYARD WORKERS

Workers in naval shipyards constitute a population with well-documented dosimetry data comparable to that of DOE-contractor facilities. Interest was focussed on the employees of naval shipyards by a report by Najarian and Colton⁽¹⁴⁾ of increased cancer mortality, including especially leukemia, among exposed workers at the Portsmouth Naval Shipyard (PNS); their report was based on a very preliminary study. Analyses of additional data for their study population have indicated that the association between radiation exposure and increased mortality, if present, is confined to cancer arising in hematopoietic tissue. The validity of that association has been disputed. Currently, the National Institute of Occupational Safety and Health (NIOSH) is cooperating with Najarian and Colton by providing them additional exposure data on their study population. Meanwhile, NIOSH is conducting an independent study of the same problem on the entire PNS population of 27,000 workers. That study is scheduled for completion by August 1980. In 1979, the Department of Energy initiated a study of workers at seven naval shipyards, which is conducted by a group at Johns Hopkins University headed by Matanoski. The study population includes about 400,000 workers; an estimated 30% have engaged in work involving exposure to radiation. Control groups will be selected from workers engaged in similar occupational activities who have not been exposed to radiation. The investigators will seek to identify confounding factors such as asbestos and chemicals for which an unusually favorable industrial hygiene data base exists at the shipyards. Smoking and medical x-ray histories will be obtained. Initial results of this large study are projected for 1983.

OCCUPATIONAL STUDIES - PROBLEMS AND JUSTIFICATION

Much of our knowledge of health effects of radiation in the human is based on studies of large populations of heavily exposed persons, such as the Japanese atomic bomb survivors, the ankylosing spondylitis patients and the radium dial painters (discussed above). In almost all instances, dose estimates for those studies were reconstructed later by indirect means. Occupational populations in the DOE-contractor facilities and naval shipyards are large and have the benefit of direct personnel dosimetry. However, the average doses to these populations of workers are small and affect the nature of the information that may be derived from studies of workers in those plants. We consider here reasons that occupational studies of such populations are performed and some of the problems that render difficult the task of deriving risk estimates from the results of such studies.

Occupational studies of active facilities, such as the DOE-contractor plants and the naval shipyards, are undertaken for several reasons. Responsibility for maintaining surveillance on the health of workers is both a moral and legal obligation. In the case of the Department of Energy, the Department is mandated by statute to "make arrangements for the conduct of research and development activities relating to the protection of health and the promotion of safety during research and production activities."⁽⁹⁾ On the other hand, a scientific and regulatory motivation is an interest in the estimation of risk when the exposure is fractionated and incurred at low levels. Because occupational exposure is usually of that nature, occupational studies should provide the most direct data for such estimation. The likelihood that results

of occupational studies will not provide an appropriate basis for the estimation of risk at low exposure levels will be addressed in the following remarks.

Problems

The most important limitation of occupational studies is the difficulty in assembling sufficiently large samples to be able to demonstrate reliably any effects that might occur. This topic has been addressed by C. E. Land in the Libassi report.⁽¹⁰⁾ In his discussion, he called attention to the fact that the sample size required to demonstrate a risk increases as the square of the decrease in risk, e.g., if one wishes to demonstrate a risk 10 x smaller than another risk, one must have a sample 100 x greater. Land also called attention to the possibility, or even the likelihood, of developing misleading (grossly exaggerated) risk estimates in the event that a statistically significant effect were demonstrated as a consequence of random variation. This type of false result would be expected to occur 5% of the time if a single statistical test (with a 5% level of significance) were repeated numerous times. In the present case, testing a data set for many correlations, such as the correlations of 15 or 20 diseases or cancer types with radiation exposure, has similar consequences. With multiple testing and a given small effect or none, random variation will provide many negative correlations that are rejected as biologically unsound, many positive but small correlations that are rejected as not statistically significant and a few falsely positive significant values (in 5% of cases) that imply a risk much greater than the true risk. The potential for reaching false conclusions

because of such randomly determined, statistically significant results may be mitigated by recognition of the impact of multiple testing on the level of significance of individual statistical tests.

A second difficulty in occupational studies concerns inadequacies in the radiation exposure data base. Cause-specific mortality is the end point that has been and probably will be investigated most extensively in these studies. A source of error in dosimetry is the lack of a central registry of all radiation exposures. During earlier years of plant operation, information regarding prior exposure was not obtained regularly for new employees. In recent years, information regarding prior exposure has been obtained, but data for plant employees do not include exposure subsequent to termination of employment. Thus, a study subject who is employed by more than one company may have only a fraction of his exposure included in the data file of any one company, again causing underestimation of doses. On the other hand, at times, zero readings were assigned values corresponding to the lowest limit of detection of the personnel monitor, leading to overestimation of doses. Another inadequacy in personnel dosimetry is the early insensitivity of detection devices, especially for neutron exposure.

Despite these and, perhaps, other flaws in personnel dosimetry, radiation exposure is probably the best monitored and documented of all occupational exposures to hazardous agents or substances. Nevertheless, the uncertainties in dosimetry cited here must be recognized in the interpretation of the results of these studies.

Confounding variables represent another problem in carrying out occupational studies. The manufacturing and research activities in the plants under consideration have often involved exposure of personnel to chemicals in certain operations. Attempts to document those exposures in a qualitative, let alone quantitative, manner have not been successful. The carcinogenic potential of most such chemicals is highly uncertain but, in some instances, could exceed that of the radiation doses incurred by workers. Exposure to carcinogenic substances may have occurred for workers during employment at plants other than those under study, such as chemical plants. Of course, smoking must always be considered as a confounding factor, especially for cancer of the lung. If, then, small carcinogenic effects are observed in a worker population, it is difficult to rule out other exposures as confounding factors to radiation. If a greater than marginal excess of cancer or of specific cancer types were observed, a major effort to investigate the role of confounding factors, however difficult, would be appropriate.

Justification

The justification for conducting occupational studies despite their problems lies in part in a societal obligation to protect workers against potentially hazardous agents or substances in the work place. Special governmental agencies such as OSHA and NIOSH have been created to implement that responsibility. If an agent or substance is suspected of being hazardous to workers, it is necessary to maintain surveillance on the health of the workers such that adverse effects will be recognized if they occur in sufficient

magnitude to permit detection. This responsibility applies equally to radiation and to other potentially hazardous agents or chemicals in the workplace.

A corollary is that responsible, qualified scientific groups be willing to undertake such studies. The latitude in the selection of methods of analyzing data sets is so great that markedly different results may stem from the analysis of a single data set. For that reason it is imperative that the various data sets be analyzed by qualified scientists using best available methods so that the results of such analyses may become part of the scientific and public record.

Because of the problems in occupational studies discussed above, we are compelled to conclude that extrapolation from studies of exposures at higher levels will provide more reliable health risk estimates than studies based on direct observation at the low levels incurred by occupational populations. However, that extrapolation, based on physical and biological models, is subject to challenge. If the results of studies of workers, with due regard for their potential deficiencies, were compatible with the results of extrapolation, confidence in the latter would be increased. If the results of occupational studies differed consistently in some respect from our expectations based on extrapolation from studies at higher exposures, there would be good reason to question the validity of the extrapolation or seek a satisfactory explanation for the discrepancy in the results. 'Consistently' implies appearance of a discrepancy in more than one and, preferably, in a few studies. Some consistency between results of studies of similar exposures is also required to avoid overinterpretation of randomly determined, aberrant results based on multiple statistical testing as discussed above.

SUMMARY AND CONCLUSIONS

Studies of occupational populations exposed to large doses of radiation, principally from the ingestion of radium by dial painters and inhalation of radon and its daughters by miners, have provided important information on the health effects of those radioisotopes. Studies of medical radiologists, military personnel exposed to nuclear tests, and factory workers exposed to thorium are in progress. Employees of DOE-contractor facilities and of naval shipyards are also under study. Personnel dosimetry data are generally available for the latter category of occupational populations. The problems involved in studies of the DOE-contractor and shipyard personnel include small sample sizes for the demonstration of effects at the low exposure levels of the workers, uncertainties in the dosimetry, and the presence of confounding factors. Reasons for conducting the studies include interest in exploring the verification at low exposure levels of results of studies of heavily exposed populations and the responsibility of the employer to maintain adequate surveillance of the health of his workers by conducting appropriate epidemiologic studies. The low level of exposure of workers in facilities where adequate personnel dosimetry records are available make it unlikely that the results of such studies can be used to provide health risk estimates in the near future.

In time, continued surveillance of occupational populations with larger numbers of deaths (as the populations age), improved systems of dosimetry and eventual recording of confounding exposures will result in improved data bases for the analyses considered here. The population exposures to be anticipated in such studies may never be large enough to be used effectively in risk

estimation. However, the studies may serve for the assessment of qualitative compatibility between the results of analyses of data from medium or high-level exposures and those from low-level, occupational exposures. They will also meet a societal need for a system of scientific monitoring of the health of workers relative to this potential hazard.

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