

Chapter 3

Public Health Impacts of Contamination From the Nuclear Weapons Complex

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Public Health Impacts of Contamination From the Nuclear Weapons Complex

OVERVIEW

People are worried. Some fear that they or their families have or will become sick as a result of living in the path of wastes and effluents released by 40 years of nuclear weapons manufacture (1-8). Others, believing that such fears are unfounded, worry that the alarms raised over contamination at the Nation's Nuclear Weapons Complex will cloud the future of communities located near weapons facilities (9, 10). Many fear that DOE does not understand the human health consequences of contamination (11-13); others believe that the whole story of environmental releases from the complex will never be known (14-23).

There is also concern that the quest for action—the desire to “do something”—will result in billions of dollars spent on senseless projects (24-28) or that attempts to clean up some sites will lead to additional environmental damage or place the health of workers and off-site populations at risk (29-31).

Fears of possible adverse health effects have been stimulated by reports of environmental contamination throughout the Nuclear Weapons Complex and by disclosures of past toxic releases that were hidden from the public for decades (32-40). Congressional debates about Department of Energy (DOE) efforts to plan and execute its environmental cleanup program have also highlighted questions related to possible public health threats (41-43).

In recent years, a series of investigations have documented lapses and inadequacies in DOE environmental health and safety practices (44-55). In August 1990, Secretary of Energy James D. Watkins announced that during the 1940s and 1950s, thousands of children had received significant radiation doses as a result of Hanford operations (56-58). This admission contrasted with previous DOE assurances that no releases posing a threat to human health had ever occurred and increased public skepticism about the accuracy of DOE claims regarding health risks

from contamination throughout the Weapons Complex.

Many of the contaminants released to the environment by DOE operations and waste management practices represent a clear danger to human health if people are exposed to sufficient doses of these materials. For example, materials known to be present at the weapons sites include radionuclides such as cesium-134 and 137; strontium-90; americium-241; plutonium-238 and 239; and uranium-234 and 238. All radionuclides are human carcinogens. Weapons contaminants also include large quantities of heavy metals such as lead (a neurotoxin and teratogen), mercury (a neurotoxin), and chromium (a carcinogen). Other chemicals found at the weapons facilities include benzene and other solvents such as toluene and trichloroethylene;¹ chlorinated hydrocarbons such as polychlorinated biphenyls, cyanide, and chelating agents (see table 2-1 in ch. 2). Unfortunately, information about the extent and magnitude of human exposure to Weapons Complex contaminants is limited.

Three conditions must be met for adverse human health effects to result from environmental contamination. First, the contaminants or their metabolites must be potentially hazardous to biological systems. Second, hazardous contaminants must be able to make contact with people; that is, the potential for human exposure must exist. Third, exposure to contaminants must occur at concentrations and for periods of time sufficient to produce biological effects. In addition, the nature of the hazards posed by specific chemicals, the degree and patterns of exposure that people experience, and the differences in individual susceptibility to toxic injury must all be considered in weighing health risks associated with environmental contamination (60). Determining whether actual harm has occurred as a consequence of toxic releases from weapons sites will depend on specific knowledge of contaminants, exposure routes, and patterns; estimates of dosages; and investigations of health outcomes among exposed

¹Solvents as a class affect the central nervous system at high doses. In addition to this general effect, individual solvents can exert specific toxic effects. Thus, benzene causes damage to blood producing cells in the bone marrow whereas certain chlorinated hydrocarbons lead to liver damage (59).

Figure 3-I—Health Issues at Toxic Waste Sites and Possible Public Health Responses

What Communities Want to Know	Public Health Responses	Key to Public Health Responses
I. Are we exposed ?	A, E	A. Exposure assessment B. Response assessment
II. Are we affected ?	B, D, E, G	o Disease cluster investigation o Cross-sectional studies
III. Did exposure contribute to effect ?	A, B, CG, E, H	C. Analytical epidemiological study D. Registries
IV. Will we be affected later?	A, C, DEF, H	E. Medical surveillance F Reference surveys o Exposures G Reference surveys o Health effects H. Risk assessment

SOURCE: D. Wagener and W. Halperin, Presentation at the National Academy of Sciences conference on "Frontiers in Assessing Human Exposure to Environmental Toxicants," Washington, DC, May 1990.

populations (see figure 3-I). At most sites, these matters remain largely uninvestigated.

As noted in chapter 2, efforts to identify, quantify, and map environmental contamination at the DOE Weapons Complex are in the early stages. Quantitative analyses of the chemical forms, concentrations, and environmental transport pathways of contaminants have not been completed at any site. Nor are the physical and chemical parameters that control contaminant migration through various media understood completely at any site.

Data describing the extent and magnitude of off-site contamination are particularly sparse. Much important information about the type and amount of past environmental releases is not yet available to regulators or to public health officials.² New waste sites continue to be discovered at the larger, older, and more complex reservations such as the Hanford Plant, the Oak Ridge Reservation, and the Idaho National Engineering Laboratory.

The mere detection of toxic environmental contamination in air, water, or soil to which people are

exposed does not necessarily imply that adverse health effects have occurred or will occur. Reliable information about the amounts of contaminants individuals are exposed to, and the amounts of toxic materials actually absorbed by the body, is especially important in assessing the effects of environmental toxicants. On the other hand, inadequacies in the scientific understanding of environmental toxicology and methodological obstacles faced by environmental health researchers make it difficult to specify with precision what levels of contamination are "safe" or to rule out the possibility of adverse health effects.

The Office of Technology Assessment (OTA) did not conduct detailed analyses of specific contaminants, environmental transport pathways, or human exposure routes at individual weapons sites. Thus, OTA is unable to judge whether or which contamination scenarios throughout the Weapons Complex constitute public health threats. Even if the necessary data for conducting such analyses were available (and they are not), this task would require time and resources beyond the scope of this report.

²In 1989, Secretary of Energy James D. Watkins agreed to make public previously classified information on Hanford Plant operations requested by the Technical Steering Panel directing the Hanford Environmental Dose Reconstruction Project (61). It is unclear whether this decision establishes a new DOE precedent of openness or is an exception to earlier policies of classifying information on environmental emissions.



Photo credit: U.S. Department of Energy

Sludge removal from injection well contaminated with tritium, TCE, and other chemicals at INEL.

OTA investigations did reveal that weapons sites contain large quantities of toxic materials and that enormous expanses of media are contaminated. Contamination includes the relatively straightforward pollution of soil and groundwater by hazardous chemicals found at many non-Federal Superfund sites, as well as extraordinarily complex contamination scenarios involving multiple environmental pathways and toxic substances that are unique to nuclear weapons manufacture (see app. A).

Currently available information about historic air emissions, releases of contaminants to soil and surface water, and environmental transport pathways indicates that human exposure to Weapons Complex contaminants has occurred (62-67) in the past, and that the potential exists for current or future exposure of humans to toxic materials (68-74).

With the exception of the findings of the Hanford Environmental Dose Reconstruction Project (HEDRP) (75), an ongoing study of radioactive releases and possible off-site exposures that occurred four decades ago, and a few reports dealing mostly with estimates of off-site radiation doses resulting from DOE activities (76-80), there is little scientific documentation of the doses of toxic substances that off-site populations have experienced or are now



Photo credit: Martin Marietta Energy Systems

Workers are protected from possible exposure to contamination during soil sampling operations at Oak Ridge.

confronting as a consequence of waste management practices and environmental contamination at the weapons facilities. Even the HEDRP results are preliminary.

OTA analyses, based on the limited evidence available, indicate that off-site health effects are an unproven but plausible consequence of Weapons Complex pollution. Given the potential threat to communities that border the complex and the level of concern that already exists in these communities, focused, aggressive investigation into past and potential health impacts at specific weapons sites is warranted.

POSSIBLE MODES OF HEALTH IMPACTS DUE TO WEAPONS COMPLEX CONTAMINATION

There are a number of ways in which the health of off-site populations might be affected, now or in the future, by environmental contamination from the Weapons Complex. Adverse health effects could occur as a consequence of exposure to off-site media that are currently contaminated with toxic substances or liable to become contaminated if measures are not taken to contain the pollution. In addition, historic releases of toxic materials that are

no longer health threats might have caused adverse health impacts. Finally, some cleanup activities could present risks to workers or to communities neighboring weapons sites.

1. *Health risks among off-site populations might result from current or future contamination.* Adverse public health impacts may result from contact with air, water, soil, or from ingestion of plants and animals that are currently contaminated with toxic substances or that will become contaminated if measures are not taken to contain pollution.

At some Weapons Complex sites, contaminants are known to have migrated off the weapons reservations (81) (see app. A). Radioactive cesium released from the Oak Ridge Reservation has been found in the sediment of a Tennessee Valley reservoir used for recreation and fishing (82, 83). Local residents have voiced concern about the possible health consequences of swimming and fishing in these waters, but there are no data estimating the amount of toxic exposure that might result from such activities.

At some sites, pollution is migrating in ways that make public contact probable unless action is taken. For example, at the Feed Materials Production Center in Fernald, OH, contaminated groundwater plumes have extended off-site (84) and are migrating toward an important source of drinking water, the Great Miami Aquifer (85). At the Savannah River Site in South Carolina, a plume of groundwater contaminated with volatile organic hydrocarbons has traveled to within several hundred yards of the fence line (86); no contaminants have been discovered in the private wells of nearby residents (87).

At some sites, contaminants are known to be “loose” in the environment, and their fates are not well-understood. For example, mercury, a known neurotoxin (88), was used in separating lithium isotopes at the Y-12 Plant in Oak Ridge, TN. More than a million pounds of mercury is unaccounted for (89, 90); a large portion of this has been deposited in the sediment of a creek that traverses the city of Oak Ridge and was used as fill for the local civic center (91). Significant amounts continue to escape from plant premises in the form of rainwater runoff (92).

A pilot study conducted in 1983 by the Centers for Disease Control failed to find evidence of abnormal mercury levels in people living around Oak Ridge (93) (see p. 84).

In some cases, population growth and development have reduced the distance between areas of on-site contamination and once-remote neighboring communities. Such a pattern is evident at the Rocky Flats Plant outside Denver, CO. The surrounding population numbered 567,000 when the plant was built in 1953; today, 1.4 million people live within 50 miles of Rocky Flats, the majority of them downwind of the plant (94).

For certain persistent hazardous chemicals and long-lived radionuclides that remain toxic for hundreds or thousands of years, potential threats to future generations must be assessed. Waste containment and cleanup strategies must consider the health impacts of possible future scenarios, such as the accidental release of stored waste, human intrusion into sites where waste is buried, or exposure to contaminants that migrate very slowly through the environment.

2. *Adverse health effects among off-site populations might also result from toxic materials released to the environment years or decades ago that pose no current exposure risks because they have since decayed, dispersed, or been diluted.* The biological effects of such releases may still be felt, however, because there can be a long lag period between exposure to toxic substances and the appearance of disease.

Documents made public in 1986 revealed that hundreds of thousands of curies of radioactivity were released from the Hanford Reservation during the 1940s and 1950s (95). Recent HERDP analyses of the environmental transport pathways of one radionuclide, iodine-131, indicate that as many as 13,000 children may have received up to 70 rads of radiation through ingestion of contaminated milk.^{3,4} Epidemiological studies are now underway to determine if the doses of radioactive iodine received by people who lived around Hanford as children can be associated with increased risk of thyroid disorders (97). Additional research is planned to investigate

3A rad is a radiation unit that describes the absorbed dose, the amount of radiation absorbed by tissue. (Modern terminology measures absorbed dose in grays (Gy): 100 rad = 1 Gy.)

⁴Preliminary dose estimates for the milk pathway show that approximately 13,000 people, the 5 percent of the study population most highly exposed, received between 1 and 70 rads due to iodine-131; the mean dosage was approximately 7 rads (96).



Photo credit: Martin Maritta Energy Systems

Water samples are taken at various depths in bodies of water impacted by the operations at Oak Ridge.

the radiation doses incurred by Native Americans who fished and bathed in the Columbia River, downstream of the release of highly radioactive effluents from Hanford's production reactors (98).

The health consequences of historic emissions could be important in developing health-based cleanup priorities if long-lived radionuclides and hazardous materials are still present in the environment. Also, a true appreciation of past releases and exposure burdens might influence the assessment of current medical conditions in communities located near weapons sites and could lead to medical surveillance programs or other interventions aimed at mitigating the effects of past practices. Understanding the consequences of such releases may also contribute to future waste management practices.

The possible effects of historic emissions are especially important to members of communities

that neighbor weapons sites, who fear that they or their children might have been exposed to toxic materials. Questions about historic releases are part of a wide range of health issues that have engaged the attention of both the public and many public health professionals. In some cases, these concerns go beyond matters that bear immediately on the direction and technical aspects of the cleanup.

3. Finally, cleanup activities could, in some cases, present a potential health threat to workers and the public. Thousands of workers may be exposed to potentially harmful contamination while cleaning up the Weapons Complex. Collection and analysis of environmental samples, remediation efforts, and the decontamination and decommissioning of buildings are all tasks that might result in workers' receiving significant doses of toxic chemicals or radiation. Extensive health and safety programs, including medical surveillance and long-term followup studies, will be required in some cases to protect workers engaged in cleanup of the weapons sites (99, 100). These issues are the subject of a separate OTA background paper (see box 3-A).

The health risks associated with cleanup activities are not limited to workers engaged in site characterization and remediation. Disturbing large amounts of contaminated soil, for example, could result in resuspension of contaminants in air. Airborne contaminants might then travel beyond the site perimeter to expose the public.

Review of Off-Site Health Studies Related to the Nuclear Weapons Complex

DOE and its predecessor agencies have sponsored research into the health effects of radiation since shortly after the end of World War II, when the Radiation Effects Research Foundation (RERF)⁵ was formed to study the health effects of ionizing radiation in atomic bomb survivors and their offspring (101). Over the past two decades, RERF has accounted for more than half of the funds spent on

⁵Data from the Radiation Effects Research Foundation have served as the basis for much of the analysis conducted by the National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR). RERF observations of the Japanese survivors of the atomic bomb constitute the largest collection of information about the long-term effects of acute radiation exposure. The size of the population under study and the relatively long period of observation make this database uniquely valuable. As the study population ages and more data become available, successive BEIR committees have revised their estimates of the cancer risks associated with exposure to low-dose radiation. Five BEIR reports have now been published, the most recent in December 1989 (102). (BEIR IV did not analyze the atomic bomb data, but instead addressed the effects of internally deposited radionuclides, chiefly radon, on uranium miners (103).)

Box 3-A—Importance of DOE Worker Data in Assessing Off-Site Health Impacts

Department of Energy (DOE) nuclear weapons production workers are important in the evaluation of potential off-site health impacts resulting from contamination at weapons sites for various reasons. Usually, workers experience occupational exposures to toxic substances that are more intense and more hazardous than exposures resulting from environmental contamination by such substances. This occurs because many jobs necessarily involve direct contact with, or proximity to, toxic materials and also because laws and regulations governing allowable occupational exposure to toxic materials are less stringent than regulations designed to protect the general public.

Health studies of workers therefore might signal the type, extent, or absence of adverse health effects that could be expected among populations experiencing less intense exposures. However, occupational studies do not provide foolproof evidence of the risk of health effects among off-site populations due to environmental contamination. Although workers generally experience higher exposure levels than do off-site populations, they are also generally healthier and harder than many segments of the general public. Children, the elderly, and people with underlying disease or certain genetic makeup may be much more vulnerable to the effects of various exposures than are healthy adults. Thus, the lower exposure of populations compared with workers is to some degree offset by variations in individual susceptibility to disease among the general public. Also, exposure to chronic, low doses of environmental toxicants may have biological effects that are not reflected by the consequences of acute, high-dose exposures in the workplace. Nonetheless, information contained in the records of DOE employees and in reports of studies by DOE contractors on segments of the DOE work force may be very valuable tools in assessing the off-site health impacts of DOE operations.

In addition, there is unique value attached to data that has been accumulated since the start of the Manhattan Project describing the health of the nuclear complex work force. It is the only database that describes the health outcomes for large numbers of people exposed to low levels of radiation over a period of decades. These characteristics make the DOE worker data extremely valuable to researchers investigating the degree of risk associated with exposure to low doses of radiation, an issue that has been controversial and has important policy implications.

epidemiologic studies⁶ by DOE's Office of Health and Environmental Research. The remainder of DOE-sponsored epidemiological research has been aimed chiefly at studying the effects of radiation on employees of nuclear weapons facilities (104). Most of this work has been conducted by scientists at DOE national laboratories; some of it has been published in peer-reviewed scientific journals (105).

Very few DOE-sponsored research studies have focused on the potential or actual impacts of various weapons site activities and releases on the health of surrounding communities. Those studies that are available focus on potential radiation effects; OTA is aware of only one study that investigated possible health impacts of toxic chemicals released by DOE operations. This section briefly reviews some of the scientific investigations, site-specific environmental surveys, and annual reports that make up much of the currently available analyses pertaining to off-site health effects due to environmental contamination at the Weapons Complex.

In 1986 a \$60-million study to assess the extent of contamination resulted in Environmental Survey preliminary reports (106). These reports were neither comprehensive nor consistent across sites, were limited largely to historical and existing data, and did not utilize standardized quality assurance or quality control procedures (107). However, the Environmental Survey did provide the first qualitative overview of environmental contamination throughout the Weapons Complex.

Each facility in the Weapons Complex prepares an annual environmental monitoring report that includes site-specific monitoring data from routine environmental surveillance activities. Almost all of the data reported pertain to radiological measurements. Calculations of radiation doses received by the off-site population as a consequence of facility operations are also reported. The focus on radiological releases and the inattention to chemical contaminants or to contamination of media such as soil and sediments, the inconsistency of reports from year to

⁶Epidemiology is the study of the distribution and determinants (e.g., causes, risk factors) of disease among human populations. By gathering and analyzing information about the frequency of exposure and illness among groups of people, inferences can be made about the causes of disease, and program for disease prevention and control can be put into practice (see box 3-C).

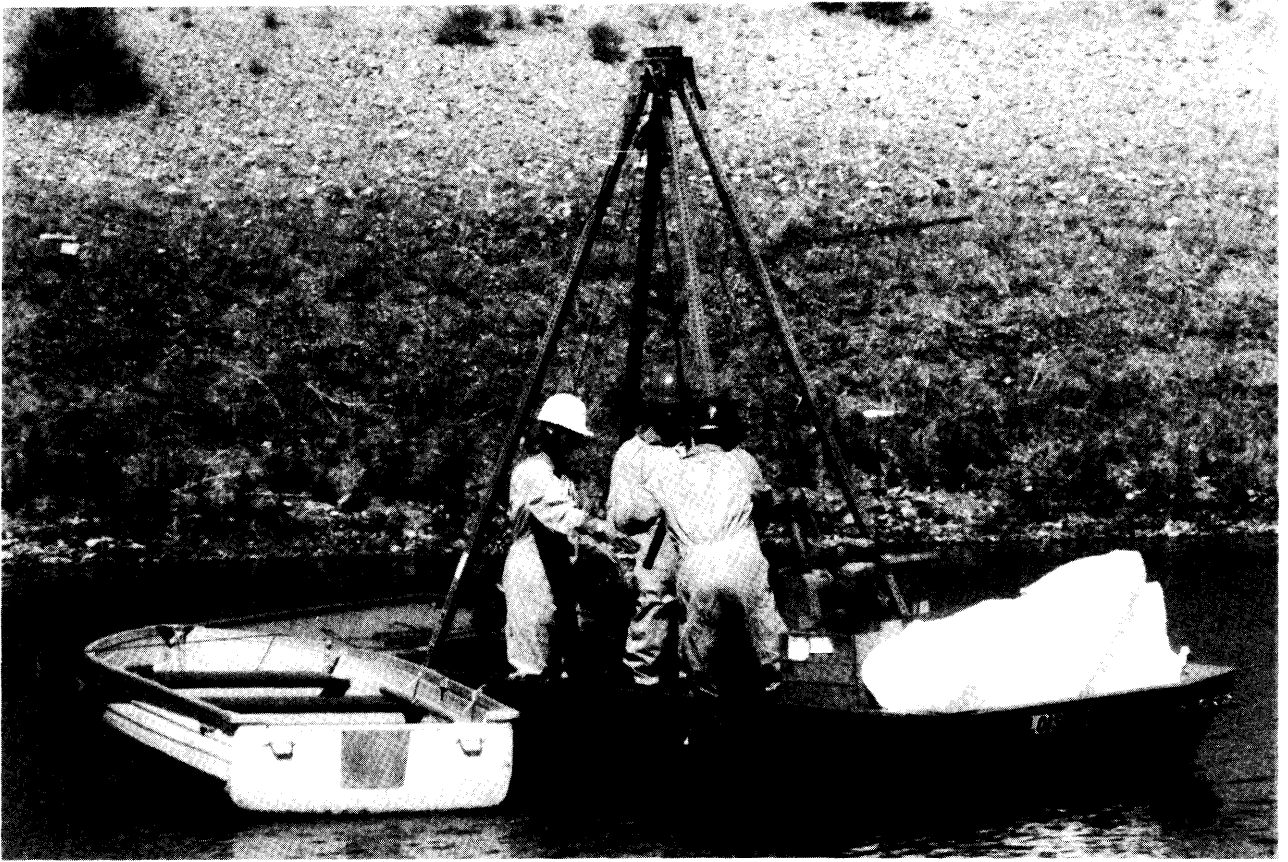


Photo credit: U.S. Department of Energy

Routine monitoring of warm waste pond at INEL test reactor area.

year at a given site (108) or among sites, the lack of rigorous quality control of data and analyses, and the absence of outside peer review limit the use of these surveys for the purposes of health effects assessment (109, 110). In addition, considerable delay has occurred between the compilation of recent site-specific Environmental Survey reports and their publication. As of mid-1990, most site survey reports for 1988 were still not available to OTA.

Over the past 18 months, a number of critiques of the environmental, health, and safety programs at the Weapons Complex have been published. The Secretary of Energy has directed "Tiger Teams" of DOE managers and contractor employees to perform environmental and occupational health and safety audits at selected DOE sites (111-117). These Tiger Team reports have varied in their approach and manner of documentation but do provide important

insights into environmental and occupational health and safety issues, as well as management and organization at selected weapons sites.

As mandated under the Defense Authorization Act of 1988,⁷ at DOE's request the National Academy of Sciences convened a Committee to Provide Interim Oversight of the DOE Nuclear Weapons Complex, chaired by Richard Meserve (118). The Meserve Report, published in December 1989, provides an overview of current strengths and deficiencies at the Weapons Complex and calls for remediation strategies based on consistent risk analyses, enhanced on-site safety programs, and substantial improvement in occupational health programs for DOE employees.

OTA has investigated the available published information on public health impacts associated

⁷Defense Authorization Act of 1988, Pub. L. No. 100-180, §3134 (1988).

with contamination from the weapons sites. Only a handful of DOE-sponsored studies have attempted to examine community health impacts of weapons site operations or releases. All were conducted in response to pressure from concerned citizens. One study was a reanalysis of a previous investigation (119, 120) reporting an excess of cancer deaths among people living near the Rocky Flats Plant in Colorado. The later study again found elevated cancer rates in certain census tracts near Denver, but the geographic pattern of excess cancers did not appear to correlate with proximity to Rocky Flats (121, 122).

Another investigation was a 1983 pilot study carried out by the Federal Centers for Disease Control (CDC) on the effects of mercury contamination at the Oak Ridge Reservation (123). This study was requested by the Tennessee Department of Health and Environment (TDHE) because of concern about the potential health effects from human exposure to soil and fish contaminated with mercury released by DOE's Oak Ridge operations. Questionnaires were used to identify individuals who were most likely to have been exposed to contamination. Urine and hair specimens were obtained from a small sample of people with probable high and low exposures: 11 hair samples were obtained from individuals whose questionnaire responses suggested high exposure and were compared with samples taken from 46 individuals with no history of exposure to contamination. Urine samples from 79 people with a history of exposure to contaminated soils were compared with samples from 99 individuals without a history of exposure. Mean mercury levels in hair and urine did not differ significantly between the two groups, nor were mercury concentrations above the levels usually associated with adverse health effects, although such levels have not been well delineated, especially in children (124).

It was concluded that the project did not demonstrate current exposure to mercury contamination. However, the number of persons tested was small. In addition, urine mercury measurements reflect only recent exposure, and the period of greatest mercury releases (1944-1977) was years and even decades prior to the study. The authors noted that their study results supported the fish ban in East Fork Poplar Creek that had been ordered by TDHE and opposed by DOE.

In 1983, Du Pent, then the DOE contractor at the Savannah River Site (SRS), sponsored an epidemiological study of cancer deaths in communities neighboring the plant (125). This cross-sectional study compared cancer death rates in counties surrounding SRS with rates in counties further away and with U.S. cancer mortality rates. No increases were observed in cancer deaths in counties adjoining the plant, nor were any trends detected of increasing death rates with increasing proximity to the plant. This study was spurred in part by public consternation over an earlier Du Pent study that showed an increase in leukemia rates among blue-collar workers at Savannah River (126), as well as an analysis by independent investigators suggesting that high-level waste tanks at SRS pose a substantial threat of explosion and consequent environmental contamination (127).

In 1984, responding to continuing community concern, DOE asked CDC to review and comment on the "feasibility and usefulness of conducting further epidemiologic studies of delayed health effects" around the plant (128). CDC was skeptical about the usefulness of epidemiological studies of off-site health effects from SRS radioactive releases because such studies would involve small populations and low dose rates and thus would have limited statistical power. Public comments at a meeting held to brief the community on CDC findings revealed continuing local concern about the health impacts of SRS operations (129).

The most ambitious and scientifically sophisticated site studies to date are the Hanford Environmental Dose Reconstruction Project (HEDRP) and the associated epidemiological investigation. HEDRP, begun in 1987 at the request of the State of Washington and neighboring Indian tribes, is being conducted by Pacific Northwest Laboratory, a DOE contractor, under the direction of a technical steering panel composed of independent scientists (130). The aim of HEDRP is to use "source terms" (estimates of the amount and type of radioactive materials released to the environment) and computer models of environmental transport pathways to reconstruct a picture of the doses of radionuclides received by individuals who lived near Hanford during the periods of highest plant emissions. The first phase of the study, which was completed in July 1990, reconstructed the air pathway and calculated dose estimates experienced by people living in the 10 counties nearest Hanford as a result of a single

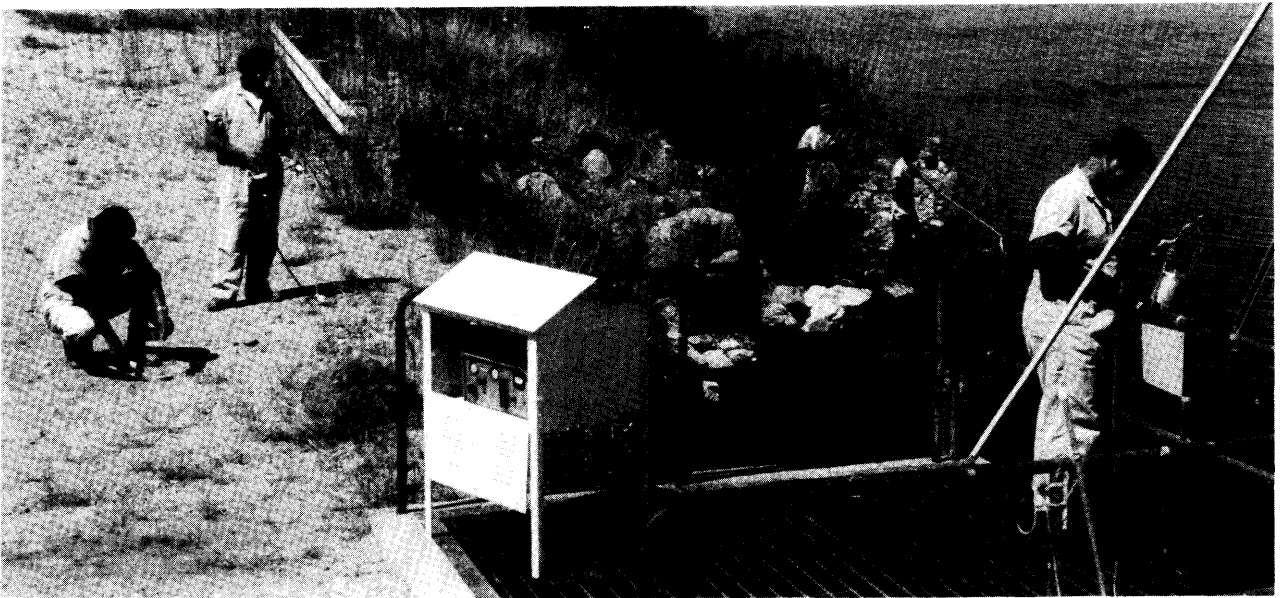


Photo credit: U.S. Department of Energy

Monitoring soil and Columbia River at Hanford.

radionuclide released to the atmosphere between 1944 and 1947. This first phase of the HEDRP study also considered radiation released to the Columbia River from Hanford between 1964 and 1966, and calculated the radiation doses that would have been incurred by residents whose drinking water came from the river.

Preliminary HEDRP findings indicate that thousands of children born in the Hanford Tri-Cities region (Richland, Kemewick, and Pasco, WA) between 1944 and 1960 may have received significant doses of radioactive iodine (iodine-131) as a result of Hanford releases (131). An associated epidemiological study that will attempt to relate the doses of iodine-131 to thyroid disease among "downwinders" is in the planning stage and will be conducted by independent investigators from the Fred Hutchinson Cancer Center in Seattle in collaboration with CDC scientists (132).

Radiation doses resulting from exposure to contaminated water or fish from the Columbia River were calculated to be much lower than those from air. However, it will be important to consider the habits and lifestyles of Native Americans who used the river during this period, because their relative dependence on and proximity to the river may have resulted in larger doses. Such investigations are planned.

A similar dose reconstruction project to analyze off-site air doses of uranium from the Feed Materials Production Center in Fernald, OH, is also in the planning stages. Like HEDRP, the Fernald study will be conducted in collaboration with CDC (133).

DOE contractors at the Idaho National Engineering Laboratory (INEL) have devised a dose reconstruction model for some off-site exposures. This model reportedly does not address all historic emissions from INEL (134). The project has been criticized for excluding public participation until recently; even State officials were not informed of the project until asked to comment on preliminary results. The project is being reviewed by a panel of independent scientists (135).

Legitimate questions exist regarding the public health impacts of environmental contamination at the Nuclear Weapons Complex. Neither the complexwide Environmental Survey, the Tiger Team analyses, the annual site-specific environmental monitoring reports, nor the few existing epidemiological studies of off-site health effects provide sufficient information to address potential public health impacts due to weapons site pollution. Available studies do not afford a comprehensive survey of contamination present throughout the Weapons Complex; information about toxic chemicals is especially lacking. Nor is reliable information

available regarding human exposure routes and dose ranges, other than the very tentative results of mercury assays at Oak Ridge and the preliminary dose estimates generated recently by HEDRP.

DOE'S Current Approach to Off-Site Health Studies

DOE has recognized that its current organizational structure for investigating possible off-site health impacts of the nuclear weapons sites is in need of improvement. In March 1990, Secretary James D. Watkins issued a directive that consolidates DOE's health research within a new Office of Health (136, 137). The reorganization is partially a response to the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) for the U.S. Department of Energy, which recommended that epidemiologic activities scattered throughout DOE be consolidated within a single office (138). According to a DOE draft of the planned reorganization, "community health studies" would be included among the responsibilities of a new Office of Epidemiology and Health Surveillance. This Office, along with the Office of Health Physics and Industrial Hygiene, and the Office of Occupational Medicine, would report through a deputy assistant secretary for health to the Assistant Secretary for environmental health in DOE (139).

The draft of the proposed reorganization does not make clear whether the scope of such "community studies" would include projects beyond those already agreed to by DOE in interagency agreements with individual States. The reorganization plan calls for independent scientists to submit competitive bids on announced Requests for Proposals. However, the draft also states that no "unsolicited proposals" would be funded by the Office of Health (140). How such arrangements would differ from the present practice of arranging for scientists at the DOE national laboratories to conduct the bulk of DOE-funded epidemiological studies is not discussed.

Efforts to increase the competence and scope of environmental health activities within DOE are commendable and necessary. The proposed reorganization foresees the three health offices having a combined total staff of 82 professionals by 1992. Because of the shortage of experts in environmental health fields (141-144), however, it will be difficult to fulfill such staff projections, even if sufficient resources are allocated.

In view of the technical complexities, time, and staff commitments required to investigate the impact of environmental toxicants on communities, it is not clear that DOE will be able to assemble the in-house capacity to carry out such studies. Furthermore, the proposed DOE Office of Epidemiology and Health Surveillance would occupy a relatively low position within the DOE bureaucracy, a status that does not indicate a major new emphasis on health effect investigations within the department.

SPEERA clearly recognized that "[t]here are limits to how well an organization can study itself without facing conflict of interest issues" (145). The proposed reorganization of environmental health programs within DOE may not take appropriate heed of such limits. If epidemiological studies are conducted only when DOE judges such investigations to be necessary, the proposed reorganization may neither encourage the participation of independent scientists, nor achieve the enhanced credibility envisioned by SPEERA for environmental health programs in DOE.

DOE'S Position on Off-Site Health Impacts

DOE officials have publicly lamented the absence of 'risk-based' priorities in the Weapons Complex cleanup and have contended that the preponderance of cleanup activities will be directed toward satisfying legal requirements, rather than addressing serious risks to the environment or to human health (146,147). DOE's attempts to develop priorities for cleanup activities across all sites are described in chapter 2. The current system gives highest priority to situations that pose, in DOE's terminology, significant "near-term" health risks. DOE asserts, however, that the contamination poses no "near-term" or "immediate" health threats.

DOE's position that Weapons Complex contamination poses "no immediate threat" to public health is asserted in the Five-Year Plan, site-specific Tiger Team reports, and elsewhere (148-150). DOE maintains this position even though it is unable to specify the precise nature and extent of past releases of radioactive and hazardous substances, cannot identify the present whereabouts and concentrations of these materials in the environment, and has only begun to document the presence or absence of human exposure to such materials. Thus, the assertion that contamination represents "no immediate threat" and no "near-term risk" is largely unsubstantiated. It is also somewhat misleading.

“Immediate health effects” or “near-term risks” are generally understood to be acute effects that occur within hours to days of exposure to high concentrations of toxic chemicals or radiation. By such a measure, smoking tobacco may accurately be said to pose no immediate or near-term risk of lung cancer.

Preliminary data indicate that, with some exceptions, much of the current and future off-site exposure to weapons site contamination involves or will involve relatively low doses of contaminants occurring over long timeframes. Such dosages and exposure patterns would not be expected to produce symptoms of “immediate” poisoning. Rather, the health impacts would be expected to take the form of (151):

- subclinical effects that, alone, would not cause illness but could disturb normal biological functions in a way that might result in disease when combined with other factors;
- increased susceptibility to common illnesses that might be indistinguishable from illness due to “normal” causes (152);
- increased incidence of certain diseases such as cancer that develop and become manifest only years or decades after exposure; and
- genetic defects manifest in subsequent generations, or reproductive dysfunctions, which are often difficult to detect and link to specific toxic exposures.

Efforts to determine whether any such effects have resulted from environmental contamination at DOE weapons sites will require active scientific investigations using sophisticated methodologies, as well as access to records of past releases, entry to the plants themselves, and financial and professional resources. Such efforts have yet to begin at most sites and have not even been contemplated at many locations.

In the absence of evidence indicating “immediate” health effects, DOE is proceeding with plans for environmental characterization and cleanup that are based strictly on regulatory requirements and schedules, some of which are specified in inter-agency agreements (IAGs). DOE’s assumption is that compliance with the law will protect against any

possible current or future off-site health impacts of contamination.

Existing regulations and IAGs may prove inappropriate as the exclusive framework for organizing the Nuclear Weapons Complex cleanup, however. Environmental contamination at the Weapons Complex is unprecedented in scope and complexity and is characterized by features that are not addressed or are inadequately addressed by existing regulations. The following section describes those processes and procedures called for by existing laws and regulations that are designed to evaluate the health impacts of environmental contamination, and evaluates their usefulness in providing a health-risk-based scaffolding around which to organize the cleanup of the weapons sites.

THE PUBLIC HEALTH ASSESSMENT PROCESS UNDER FEDERAL AND STATE REGULATIONS

Introduction

A number of specific types of evaluations and procedures are mandated by environmental laws, regulations, and interagency agreements for assessing the possible human health impacts of weapons site contaminants.⁸ The formidable technical challenges involved in determining whether waste storage facilities or uncontrolled contamination pose health threats are reflected in the complexity of the regulations governing the health assessment processes. The Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control, and State health departments all have roles to play in the health assessment of environmental pollution at the weapons sites. In addition, the regulatory landscape is dynamic; some regulations are in transition, others have never before been applied on the scale required by the DOE cleanup, and negotiations towards health studies agreements are still taking place between some States and DOE. Nonetheless, it is important to understand the components of the health assessment process stipulated by existing regulations because DOE is relying on this process to guide and shape the cleanup.

⁸The regulations are, in all, those promulgated under the Resource Conservation and Recovery Act, as amended (RCRA), and the Comprehensive Environmental Response, Compensation and Liability Act, as amended (CERCLA or “Superfund”). State laws also apply in some cases. See ch. 2 for discussion of these regulations.

The first set of regulatory fences that guard against adverse ecological or health impacts due to environmental contamination consists of regulations or “standards” that set allowable upper limits for specific chemicals in specific media. For example, EPA Primary Drinking Water Standards permit a maximum level of 0.002 milligram of lead per liter of drinking water.⁹

Environmental standards are derived from toxicological data according to conceptual rules and assumptions formulated principally by EPA. These formulations are designed to take account of gaps and scientific uncertainties in the available data and variations in exposure patterns and individual susceptibility to disease. The basic idea behind chemical-specific standards and guidelines is that noncarcinogens cause toxic effects only if exposure levels exceed a certain “threshold.” The threshold for a specific chemical can be identified experimentally and used as the basis for setting regulatory standards and guidelines (153).

Carcinogens are regulated differently (154-156). Carcinogens are treated as though they are capable of causing a finite risk of cancer at any exposure or dose level: there is no threshold below which exposure is considered to be safe. EPA has derived methods for estimating a substance’s cancer-causing potency, the quantitative relationship between dose and response (157).

In practice, the EPA cancer potency number, called a slope factor, is multiplied by the amount of exposure to a substance that could be expected under conditions present at a given waste site. The resulting number is an estimate of the upper bound probability of the excess lifetime cancer risk as a result of that exposure. Superfund requires that the calculated individual lifetime risk for excess cancers at a remediated site be no greater than one chance in 10,000 (158). Similarly, media-specific standards governing allowable levels of contamination with carcinogens are designed so that human exposure to such pollution would not produce more than one excess cancer per 10,000 people exposed.

The application of recommended exposure standards and guidelines to real-world situations provides a useful yardstick of some probable potential health impacts. However, legal standards and recommended guidelines are not always well-validated by

scientific evidence (159- 161). Approximately 60,000 chemicals are used commercially (162); human data are available on the cancer-causing potential of about 60 substances (163). Animal and in vitro studies of carcinogenicity have been conducted on a somewhat larger number of substances (164). Nonetheless, there is no information about the cancer-causing potential of 75 to 85 percent of all chemicals in commercial use (165).

Even less information is available concerning the nonacute, noncarcinogenic effects of such chemicals. Cancer deaths and acute poisoning are clearly important biological end points, but scientists have become increasingly attentive to other health outcomes, such as the impact of toxins on the neurological, immunological, and reproductive systems (166, 167). A recent OTA report contends that neurotoxicological effects, in particular, have been underemphasized by scientists and regulators (168). Current laws, reflecting the limitations of scientific knowledge, focus almost exclusively on cancer fatalities and acute (i.e., high-dose, short-term exposure) effects.

OTA investigations indicate that, where human contact with environmental contaminants from the weapons sites occurs, it is likely to involve low-dose, chronic exposures or episodic exposures to somewhat higher doses. The biological effects of such exposure patterns are difficult to study, even in laboratory settings, and are poorly understood. It is therefore difficult to craft chemical-specific regulatory standards that effectively guard against the full range of possible health effects and exposure conditions.

Uncertainties in the scientific understanding of the health effects of environmental contamination constitute one reason why compliance with promulgated regulatory standards may be insufficient to ensure the protection of public health. In addition, some regulatory standards take economic benefits, the costs of implementation, and technical feasibility, as well as health considerations, into account and are not intended to designate “safe” levels of exposure (169). Also, different agencies and different regulations within agencies incorporate differing standards of “acceptable risk,” which further confuses the meaning of allowable exposures or con-

⁹Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities, 40 CFR §265, App. III (1989).

taminant concentration limits set by chemical- or media-specific standards (170).

Regardless of how a particular standard is determined, it constitutes a sharply defined rule, a regulatory “line” that cannot be crossed. EPA does grant waivers from meeting particular standards in some circumstances, but the reasons for not achieving the standard must be compelling.

Within the Superfund program, the chemical-specific, media-specific standards and guidelines set by Federal authorities and by States are collectively known as ARARs (“applicable or relevant and appropriate requirements”). The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) requires that every Superfund site comply with all ARARs, including both Federal and State regulations, in designing remediation goals (171).¹⁰ Thus, the first step in evaluating the health risks from a Superfund site involves comparing contamination levels measured at that site against pertinent standards. However, compliance with all ARARs is still likely to leave many chemicals and situations unaddressed.

For this reason, a second type of approach to environmental health impacts was incorporated into the regulatory framework. This approach involves site-specific investigations and evaluations of releases and waste sites at which health impacts are found or suspected. Site-specific assessments mandated by existing regulations include quantitative risk assessments carried out by DOE and its contractors at Superfund sites and reviewed by EPA, health assessments conducted by the Agency for Toxic Substances and Disease Registry at Superfund sites, and some site-specific health studies negotiated by States as part of IAGs.

There is no clear scientific consensus on how best to study the health effects attributable to environmental contamination. Formidable logistical and methodological obstacles attend all such efforts. Site-specific investigations require that information of many different kinds, usually gathered for purposes other than health assessments (e.g., CERCLA remedial investigations and feasibility studies), be collected, evaluated, and integrated into a composite picture (see box 3-B). Source terms—records or information about the identity and quantity of contaminants that originally entered the environment—



Photo credit: U.S. Department of Energy

Water tank inspection and cleaning at the INEL Radioactive Waste Management Area.

are often incomplete or unavailable. Exposure measures—reliable ways of identifying who was exposed to the contaminants and in what amounts or patterns—are difficult to obtain. The populations involved are sometimes too small to demonstrate statistically significant differences in health status among exposed v. nonexposed groups (see box 3-C). In some cases, “exposed” groups are diluted by individuals moving into and away from the site under study (see box 3-D). Health outcomes—the biological effects to be investigated—are also problematic. Current limitations on the scientific understanding of toxicology make it difficult to associate specific symptoms, physical findings, or diseases with particular toxic exposures. Here again, small populations impose methodological barriers to reaching clear conclusions.

Partly because site-specific investigations of environmental health effects are so difficult to design and conduct, this type of public health intervention has not been emphasized in environmental laws. Nonetheless, there is no substitute for site-specific studies in evaluating the health impacts of a particular waste site or environmental release. Only site-specific investigations can provide the environmental characterization data, demographic information, and health outcome measures needed to evalu-

¹⁰42 U.S.C.A. §6921(d) (West Supp.1990).

Box 3-B—Tracing the Toxic Trail From Contaminant Source to Health Effects

Linking an environmental contaminant to a particular human health effect requires tracing a long and complicated trail from the original source of a pollutant to the particular symptom, disease, or other biological end point suffered by an individual or a population. The trail maybe years or even decades old, and documentation of the original source term may not be ideal. The course of a contaminant's progress may literally be underground, where its route and direction cannot be visualized directly, or the pollutant may have been dispersed by winds long ago. Once a chemical or radionuclide is loose in the environment, it can interact with other substances, change chemical form, become diluted, transfer from one medium to another, piggyback on other substances that transport it long distances, or accumulate in geophysical sinks or in plants and animals. Tracking such escape routes, mapping the present whereabouts of the contaminant, and designing measures to contain or eliminate the pollution are the purposes behind the remedial investigation/feasibility study (RI/IX) and facility investigation (RFI) processes of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA), respectively. Virtually every aspect of the cleanup effort thus far has involved efforts to identify, trace, and quantify environmental contamination.

Figure 3-2 traces a contaminant from the source of pollution to the observable health effect. Most of the requirements stipulated by environmental regulations, and all Department of Energy (DOE) cleanup efforts to date, address the top half of the diagram: assessing the path and behavior of contaminants as they move into the environment and become potentially accessible to human contact. Very little effort has been directed toward investigating the *effects* of the contamination on human health or the environment.

Environmental health assessments focus on the bottom half of figure 3-2, that part of the "toxic trail" leading from human exposure to health effect. For health investigators, information describing the types and whereabouts of the contamination is just the beginning of the puzzle. Environmental health assessments attempt to follow the progress of an environmental toxicant from its presentation in the ambient environment at the point of potential human exposure through its absorption into the body and subsequent metabolism, accumulation, or elimination, and to relate these phenomena of molecular biology to observable expressions of dysfunction or to overt disease.

Ultimately, the scientific challenge is to determine as accurately as possible each term in the path that links the source of the contaminant with the particular biological end points or health effects, and to understand the molecular mechanisms that connect them. However, the present state of scientific knowledge regarding the effects of exogenous chemicals on human biology is very limited. Understanding the connections at the molecular level between the terms in figure 3-2 is, at best, a blurred picture and often a black box. Moreover, the nature of the terms in the bottom half of the figure is frequently unknown as well.

Because, in practice, many terms in figure 3-2 are estimates, guesses, or simply unknown, environmental health assessments must be designed and interpreted carefully, lest the many unknowns and the large ranges of uncertainty in individual pieces of the assessment combine to yield ambiguous or even misleading results. Judgments are inevitably integrated into any assessment of environmental health effects, whether the methods used involve large epidemiological studies or the most rigidly codified quantitative risk assessments. The scientific credibility of such assessments is enhanced when those judgments are made explicit and research efforts are conducted in an open, unbiased manner.

Analytical Components of Environmental Health Assessments

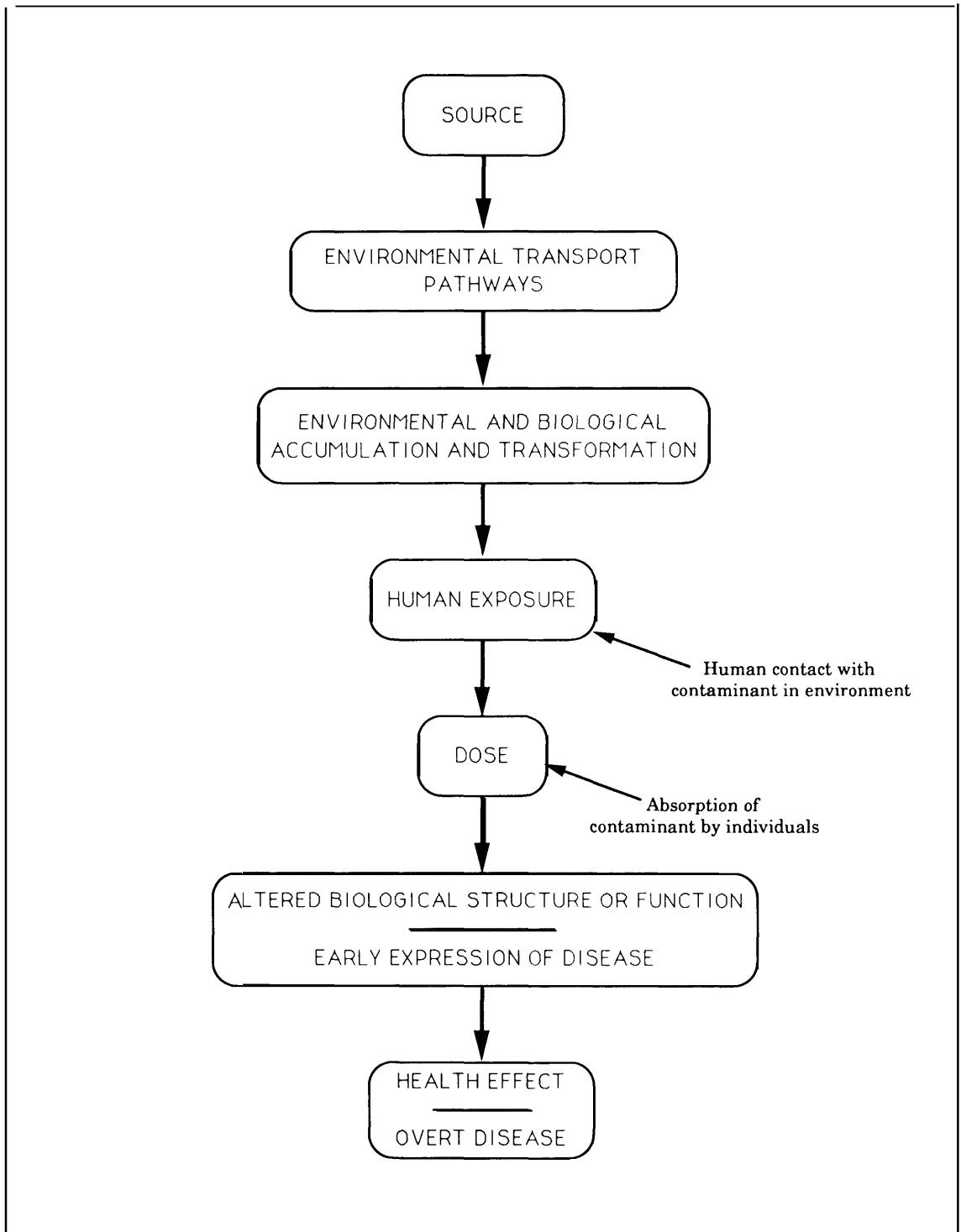
Environmental health assessments must rely on what is known about the toxic effects of a chemical, or similar chemicals, to fill in the blanks and sketch tentative connections between exposure and disease. The aim of all analytical methods that seek to understand and predict the linkages between exposure to environmental agents and human health is to devise a legitimate means of relating a given exposure to a given biological effect *without knowing* all the terms in the bottom half of figure 3-2.

All methods of assessing environmental health effects can be thought of as consisting of three key elements:

1. determining exposure and dose,
2. determining health effects, and
3. determining dose-response relationship (a term that quantitatively relates dose and effect).

Different environmental health assessment methodologies are distinguished by the ways in which these terms are derived and utilized. Wrying situations, purposes, and priorities may render some methods more suitable than others in identifying the terms and interpreting their meaning.

Figure 3-2—Tracing the Toxic Trail



Box 3-C—All About Environmental Epidemiology

Epidemiology is the study of the occurrence and distribution of disease among population.¹ Epidemiology rests on the premise that disease does not occur randomly among populations but instead afflicts certain people at certain places and times according to the underlying causes of the illness.² By studying these relationships, epidemiologists can achieve important insights into the association between certain exposures or risk factors and the occurrence of disease. Such insights can provide valuable tools in the prevention and control of disease.

Traditionally, epidemiology has focused on diseases of infectious origin such as cholera and Acquired Immune-deficiency Syndrome (AIDS), or on some chronic diseases such as lung cancer and heart disease. Recently, there has been increasing interest in applying epidemiological methods to investigations of disease among populations exposed to environmental toxicants.

Environmental epidemiologic studies consist of several analytical components. For example, groups may be identified according to their exposure to a certain substance, operation, waste facility, etc. The occurrence of certain health outcomes, such as age-related mortality or cancer incidence among exposed groups, is investigated and compared with the health effects experienced by groups who were not exposed to the substance or process in question. If a positive association is discovered between a certain exposure and a particular health effect, and if the degree of exposure can be quantified, the results of epidemiological studies can be used to derive dose-response relationships, which in turn can be incorporated into quantitative risk analyses.

Epidemiological studies are less constrained by the limits of existing knowledge than are quantitative risk assessments (QRAs). In theory, the association between any exposure and any health effect could be examined by an epidemiological study; it is not necessary for such an exposure-effect linkage to have been previously noted or for dose-response data to be documented in the scientific literature. Thus, for example, the incidence of cancer among people exposed to a certain combination of toxic chemicals can be investigated in the absence of specific toxicological data about the effects of such complex exposure. If a positive association between exposure and effect were detected, laboratory studies could then be focused on the consequences of such exposure. In contrast, quantitative risk assessments could not even consider the possible outcomes of complex exposures unless dose-response data were already available linking the exposure and the health effect in question.

For example, workers exposed to coke oven emissions suffer unusually high rates of lung and genitourinary cancer compared with coworkers of similar characteristics (including smoking status) who are not exposed to these emissions.³ Coke oven emissions consist of a complex mixture of hydrocarbons and metals, including benzene, cadmium, arsenic, chromium, and beryllium. The toxicology of this stew of substances is imperfectly understood.

A quantitative risk assessment of the hazards of coke oven emissions would attempt to identify the health effects of exposure to each chemical ingredient, assess available dose-response information for each substance, quantify human exposure to each of these component chemicals, and sum the resulting chemical-specific cancer risk estimates.⁴ Not only would such a task require considerable effort, but the uncertainties, extrapolations, and data gaps would likely make it very difficult to detect any actual risks—especially because the genitourinary cancers observed in humans are not observed in animal experiments.⁵ One advantage of epidemiological studies is their ability to consider the health consequences of exposure to substances or combinations of substances whose toxic effects are not well understood. This may be important in designing health studies pertinent to Weapons Complex contamination, where exposure to combinations of potentially toxic materials and to patterns of exposure that are not easily tested in lab studies are at issue.

Pitfalls of Environmental Epidemiology

The flexibility of epidemiology to focus on the particular toxic exposures and health effects of interest is offset by other methodological drawbacks, however. In conducting epidemiological studies, it is necessary to specify

¹J. Mausner and S. Kramer, *Epidemiology An Introductory Text*, 2d ed. (Philadelphia, PA: W.B. Saunders, 1985), p. 1.

²J. Greenhouse, "Commentary on Epidemiological Methods of Environmental Exposure and Specific Disease," *Archives of Environmental Health*, vol. 43, 1988, p. 109.

³U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, *Fifth Annual Report on Carcinogens--Summary*, NTP 89-239 (Rockville, MD: Technical Resources, Inc., 1989), p. 290.

⁴U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, *Guidelines for the Health Risk Assessment of Chemical Mixtures*, 51 Federal Register 33992, Sept. 24, 1986.

⁵U.S. Department of Health and Human Services, op. cit., supra note 3.

exposure accurately—to identify who is exposed and who is not. If an appreciable number of people who are actually exposed are missed by investigators, or if exposed and nonexposed individuals are incorrectly labeled, the likelihood of detecting any true association between the exposure and the effect decreases.^{6 7}

The need to document exposure to environmental toxicants accurately—and quantitatively, if possible—is recognized by the scientific community. This issue was recently addressed at a conference held by the National Academy of Sciences.⁸ It is very difficult however to reliably document individual exposure to environmental pollutants. Obtaining information about the degree of individual exposures, or quantitative assessments of exposures over time is especially difficult. The efforts of the Hanford Dose Reconstruction Project have been directed towards creating a computer model that calculates amounts of toxicants released to the environment and attempts to trace such pollutants through various media pathways over time, and ultimately, to construct estimates of individual doses of such toxicants. Such “dose reconstruction” will be the first step of an epidemiologic study of the health effects associated with exposures to radionuclides released from Hanford.

Although dose reconstruction of exposures to radionuclides is technically complicated and invested with much uncertainty, radiologic environmental dose reconstruction is far more advanced than efforts to assess individual exposure to toxic (non-radioactive) chemicals. Much recent research activity has focused on developing biological markers of exposure.^{9 10} Also, sophisticated computer models of exposure allow representation of individual “microenvironments” and consider indirect, but potentially significant, exposure routes such as the inhalation of organic solvents volatilized during showering with contaminated water.^{11 12}

The difficulty of successfully documenting health outcomes among groups under study also plagues epidemiologists. If the occurrence of health effects over time cannot be tracked with accuracy because a significant portion of the exposed or nonexposed groups are “lost to followup,” the chances of detecting any true association between the exposure and the effect decrease. These problems are often encountered when the health effects of interest occur only years or decades after initial exposure. Examples of such long-latency effects include cancers that appear 5 to 20 years after the exposures that caused them, and genetic defects that appear only in subsequent generations.

The detection of adverse health effects resulting from exposure to environmental toxicants is also complicated by individual variation in susceptibility to disease. Genetic factors, age, sex, the presence of underlying diseases, concomitant toxic exposures, and personal habits can all influence the expression of disease in an individual. Although such factors are difficult to identify and document, they can have a significant impact on the expression of overt illness among populations.

Quantitative estimation of the comparative measure of disease among exposed v. unexposed groups involves the use of statistical analyses. Statistical analyses endeavor to determine the likelihood that observed results are simply random events that do not truly indicate a real difference in baseline risk and, also, attempt to delineate (i.e., place “confidence intervals” around) the whole range of results compatible with the observed data. There are many opportunities for debate about which statistical strategies are appropriate for analyzing a given data set. Witness, for example, the long controversy over the risks associated with exposure to low-dose ionizing radiation.

The ability of an epidemiologic study to detect real increases in health effects due to exposures rests to some degree on the size of the populations studied. Obviously, more data points—more people exposed, more people with

⁶B. Barron, “Effect of Misclassification on Estimates of Relative Risk,” *Biometrics*, vol. 2, 1977, pp. 414-418.

⁷B. Gladen and W. Rogan, “Misclassification and the Design of Environmental Studies,” *American Journal of Epidemiology*, vol. 109, 1979, pp. 607-616.

⁸National Academy of Science, “Frontiers in Assessing Human Exposure to Environmental Toxicants,” Washington, DC, May 15-16, 1990.

⁹Subcommittee on Pulmonary Toxicology, Committee on Biologic Markers, National Research Council, *Biologic Markers in Pulmonary Toxicology* (Washington, DC: National Academy Press, 1989).

¹⁰Subcommittee on Reproductive and Neurodevelopmental Toxicology, Committee on Biologic Markers, National Research Council, *Biologic Markers in Reproductive Toxicology* (Washington, DC: National Academy Press, 1989).

¹¹L. Wallace, E. Pellizzari, T. Hartwell, et al., “The Influence of Personal Activities on Exposure to Volatile Organic Components,” *Environmental Research*, vol. 50, 1989, pp. 37-55.

¹²I. von Lindern, K. Steward, M. von Braun, et al., “Use of a Geographic Information System in Selecting Residential Properties for Remediation at the Bunker Hill NPL Site,” *Proceedings of the 10th National Conference on Management of Uncontrolled Hazardous Waste Sites*, Superfund '89, December 1989, pp. 430-435.

Box 3-C—All About Environmental Epidemiology—Continued

cancers, etc.—enhance the precision of the results and increase the likelihood that they accurately reflect the true situation in the entire population of exposed people. Similarly, more data decrease the chances that observed results are merely some peculiarity of the individuals sampled in the study.

The strength of the true association between the exposure and the health effect under study (i.e., the risk of disease if exposed compared with the risk without exposure) is the next important factor in determining whether an epidemiological study can detect “real” risks. If the risk of disease with exposure is very much greater than the risk of disease without it, large increases (i.e., exposure increases the baseline risk 10 to 100 times) may be detectable with small or moderate-size study populations. If, however, exposure increases the risk of disease by a factor of 10 or less, extremely large populations may have to be studied before adverse effects are detectable.

Herein lies another Achilles’ heel of environmental epidemiology. Even if exposure can be documented adequately, epidemiology’s lack of sensitivity—its inability to detect a small or moderate health effect even when the effect is truly present—limits the usefulness of such studies. As one environmental health professional put it:

The definition of a public health disaster is an adverse effect so enormous that an epidemiological study can detect it.¹³

¹³D. Ozonoff, Professor and Chief, Environmental Health Section, School of Public Health, Boston University, personal communication, Jan. 12, 1990.

ate possible links between environmental contaminants and health effects in a particular community.

What follows is a discussion of the limitations that beset existing chemical-specific and media-specific environmental regulations in affording public health protection from contamination at the weapons sites, followed by descriptions and evaluations of the major site-specific types of health evaluations mandated by the laws and interagency agreements applicable to cleanup of the Nuclear Weapons Complex.

Limitations of Existing Chemical- and Media-Specific Standards

Environmental laws are necessarily limited by the sophistication of the science that frames them. Pollution at the Nuclear Weapons Complex includes many features that were unanticipated, and thus are not successfully addressed, by existing statutes and regulations, namely:

- a multiplicity of contaminants that pollute various media and thus necessitate accounting for many possible exposure routes to determine total exposure burdens;
- historical releases of contaminants that may not be detected in the course of regulatory compliance but can contribute significantly to the overall exposure burden of off-site populations; and

- contamination of large areas of soil and surface water sediments with radionuclides (e.g., plutonium, americium, cesium)—situations that are not addressed by Federal statutes.

In addition, standards governing exposure of the general public to off-site radiation released from DOE facilities have not been updated promptly to reflect new health risk information, and many are concerned about DOE’s self-regulatory role in setting and enforcing radiation standards.

Media-Specific Standards Do Not Address Total Exposure Burdens

The possible health impacts of exposure to weapons site contaminants depend on the toxic effects of the total exposure burden resulting from all possible sources and pathways. Current laws are not well suited to consideration of total exposure burdens.

Some off-site exposures due to weapons site contaminants may involve more than one contaminant. For example, sediments in lakes and streams surrounding the Oak Ridge Reservation contain both radionuclides and polychlorinated biphenyls (PCBs) (172). The biological consequences of such multiple exposures may be very different from the effects of individual contaminants. Once inside an organism, environmental toxins can accumulate, interact by impinging on the same organ system, or alter the metabolism of other toxins (173).

Box 3-D—Exposure Assessment and Misclassification

In infectious disease epidemiology, exposure is a relatively clear-cut concept; there are usually simple and reliable medical tests that identify the presence of antibodies, bacteria, or other markers of definite internal exposure or infection. Environmental epidemiologists, on the other hand, often have to make do with very crude measures of exposure. For example, “exposed” and “unexposed” groups might be determined by separating people into categories based on the distance between residence and a source of pollution. This is clearly not a very precise way of identifying true exposure status.

Incorrect assessments of who is and is not exposed to an environmental contaminant can have serious consequences for epidemiological investigations. Misclassification of exposure status—incorrectly **assigning** people to “exposed” or “nonexposed” categories—can obscure the actual association between exposure and the risk of adverse health effects. Misclassification always decreases the apparent risk of getting sick if one is exposed: the relative risk appears lower than it truly is. ¹The effects of such misclassification become more serious as the true relative risk increases. ²

For example, consider a study, sponsored by EPA, of plutonium burdens among people living around the Rocky Flats Plant. ³This study analyzed the plutonium burdens of autopsy tissue taken from people who had resided in the vicinity of Rocky Flats and compared the results with plutonium burdens measured in the bodies of people who lived farther away. It was discovered that the amounts of plutonium in lung and liver samples were not appreciably different in people who lived in areas distant from the plant compared with the “study group” of people who lived closer to the plant.

However, the majority of autopsy specimens came from subjects residing in areas distant from the plant—only three subjects had lived within 10 kilometers of Rocky Flats. Thus the study group—people assumed to be exposed to whatever emissions were coming from the plant—was diluted by samples from subjects who did not really live very close to plant premises. Such dilution of the exposed group by unexposed subjects would obscure any true risk of excess plutonium burdens that “exposure” to Rocky Flats operations (i.e., residence within 10 kilometers of the plant) might confer.

Exposure assignments could also be affected by migration in and out of the area around Rocky Flats. If, for example, a number of long-term residents had moved out of the area before the study began, or if significant numbers of people in the study had only recently settled around Rocky Flats and thus had little opportunity to be exposed to plant emissions, exposures among the group residing near the plant when the study began would miss many of the more highly exposed individuals and be diluted by the inclusion of newcomers.

The authors of this study recognized the possibility of misclassification, among other study limitations, and concluded that “we cannot rule out the possible conclusion that people who lived near the southeast of RFP [Rocky Flats Plant] and near to the plant for the last 5 years of life, may have a larger proportion of weapons grade Pu [plutonium] in their lungs than did people who lived farther away with a pattern similar to that found in the soil in the same area.

Biological markers are indicators of changes in cellular or biochemical components or processes, structure, or function that are measurable in biologic systems or samples. There are three types of biologic markers: those that indicate an organism’s *exposure to an* exogenous substance, those that indicate an effect of such exposure, and markers that indicate *susceptibility to an* organism’s ability to respond to an exposure. ⁵Biomarkers are desirable as indicators of exposure because, to the extent that they are sensitive and specific, they permit assignment of individual exposure status and make misclassification errors less likely.

In practice, direct evidence of individual human exposure—i.e., evidence of actual contact between the **Pollutant** and an individual—is rarely sought or measured when complying with environmental regulations or

¹B. Barron, “Effect of Misclassification on Estimates of Relative Risk,” *Biometrics*, vol. 2, 1977, pp. 414-418.

²B. Gladen and W. Rogan, “Misclassification and the Design of Environmental Studies,” *American Journal of Epidemiology*, vol. 109, 1979, pp. 607-616.

³J. Cobb, et al., *Plutonium Burdens in People Living Around the Rocky Flats Plant*, U.S. Environmental Protection Agency, EPA-600/4-82-069, 1979.

⁴*Ibid.*, pp. 198-199.

⁵Subcommittee on Pulmonary Toxicology, Committee on Biologic Markers, National Research Council, *Biologic Markers in Pulmonary Toxicology* (Washington, DC: National Academy Press, 1989), pp. 2-3.

Box 3-D—Exposure Assessment and Misclassification—Continued

conducting quantitative risk assessments. Instead, indirect indicators, usually computer models of exposure estimates derived from environmental monitoring data, are used to estimate exposure. Advanced computer capabilities and analytic techniques are now available that permit reasonably accurate modeling of environmental transport pathways followed by various contaminants.⁶

To complicate exposure assessments further, a long lag period or latency may occur between the time of exposure to an environmental toxicant and the manifestations of biological effects or the appearance of disease. Until the lag period has elapsed, health assessments of diseases, such as cancer, that are observed only after a latency of decades will not be informative.⁷ It is difficult, however, to accurately reconstruct exposures that occurred years or decades in the past

Another issue that environmental health assessors must confront is the matter of exposure to combinations of contaminants. Communities located near nuclear weapons plants may be exposed to several environmental contaminants. The combined effects of such multiple exposures can be very different from the effects seen in response to individual contaminants. Once in the body, environmental toxins can accumulate, interact by impinging on the same organ system, or alter the metabolism of other toxins so that the biological impact of multiple exposure may differ significantly from the effect of exposure to individual substances.⁸ Investigators attempting to achieve a comprehensive picture of the health consequences of exposure to multiple contaminants must use professional judgment in anticipating what biological response(s) might result from such exposure burdens and exercise caution in selecting or rejecting which specific health effects to study.

Long-lived biomarkers could, in principle, provide an accurate reflection of integrated exposure patterns and cumulative exposure levels. Levels of polychlorinated biphenyls (PCBs), for instance, persist in human fat cells for decades. Samples of adipose tissue can, therefore, provide an estimate of long-term exposure to PCBs.⁹ In practice, however, few persistent biomarkers of exposure to environmental contaminants are available.

Another issue of relevance to the investigation of toxic exposures and their effects on populations is what statisticians call "variability." Exposures are seldom homogeneous through time and across populations. Instead, there are often episodic exposure excursions that may be many times greater than the average. The release of 7,500 curies of iodine-131 from Hanford in 1949¹⁰ and instances of plutonium emissions from Rocky Flats due to serious fires in 1957 and 1969¹¹ are examples of such episodic releases. Because the pattern and intensity of exposure are so important in determining biological effects, computations based on average monitoring data may fail to represent real-world conditions accurately. It is difficult to design laboratory experiments or computer models that mimic such episodic exposure patterns.

⁶P. Liroy, "Assessing Total Human Exposure to Contaminants," *Environment, Science, and Technology*, vol. 24, No. 7, 1990, pp. 938-945.

⁷C. He@ "Uses of Epidemiological Information in Pollution Episode Management," *Archives of Environmental Health*, vol. 43, 1988, pp. 7S-82.

⁸U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, *Guidelines for the Health Risk Assessment of Chemical Mixtures*, 51 *Fed. Reg.* 33992, Sept. 24, 1986.

⁹C. Klaassen, et al. (eds.), *Casarett and Doull's Toxicology*, 3d ed. (New York, NY: MacMillan Publishing, 1986), p. 41.

¹⁰Technical Steering Panel, Hanford Environmental Dose Reconstruction Project, "Report of the Source Term Subcommittee," *Annual Report, 1988, Appendices* (Olympia, WA: 1988), p. 18.

¹¹S. Poet and E. Martell, "Plutonium-239 and Americium-241 Contamination in the Denver Area," *Health Physics*, vol. 23, 1972, pp. 537-548.

The effect of exposure to combinations of contaminants is an area that is seldom addressed and little understood by scientists. There is little scientific basis for predicting the effects of mixtures of contaminants on biological systems (174). In particular, no convincing scientific rationale exists for predicting the health risks due to a combination of radionuclides and toxic chemicals (175-177). The guidance for performing quantitative risk assess-

ments under CERCLA recommends that gaps in the understanding of such phenomena be dealt with by simple addition of predicted health effects (178). This pragmatic approach may not reliably predict the actual impact of combined exposures, however.

Multiple environmental media are contaminated at all weapons sites, providing many potential pathways for human exposure. Most regulatory

standards, however, are media specific. Standards set allowable pollution limits for individual contaminants in a single environmental medium, such as air or water, and do not allow consideration of the total exposure burden resulting from contact with all contaminated media.

Quantitative risk assessments conducted under CERCLA¹¹ do require that the potential impact of all exposures from all media be considered. However, to separate individual weapons sites into manageable packages, CERCLA allows contaminated areas to be divided into “operable units.”¹² The tendency for regulatory standards to focus on individual contaminants in a single medium and for Superfund efforts to concentrate on operable units makes it difficult to synthesize, within the regulatory framework, a picture of total exposure from all possible contaminated pathways.

Regulations Do Not Address Historical Emissions

Neither the Resource Conservation and Recovery Act (RCRA) nor CERCLA addresses the contribution of historical emissions to the total exposure burden; both examine only current or projected pollution. Contaminants released from a site in the past, which have since decomposed, been diluted, or migrated off-site and are not now detectable—are ignored (179). Thus, the release of hundreds of thousands of curies of radioactivity into the air around Hanford in the 1940s and 1950s—direct measurement of which is now impossible—is not considered under these laws, even though the health impacts of such releases may have been considerable and may still be detectable and medically treatable.¹³

The Agency for Toxic Substances and Disease Registry has the statutory authority to consider the health impacts of past releases of environmental contaminants (180). In practice, however, it often lacks the resources needed to collect and independently review historic source-term information and environmental monitoring data.

Regulations Lack Guidelines for Radionuclides in Soils and Sediments

Existing laws fail to address some of the contamination at DOE weapons sites. In particular, there are no Federal standards for setting allowable limits of radionuclides in soil and sediments. Large quantities of soil at Hanford (181) and the Nevada Test Site (182), and lesser amounts at Rocky Flats (183), the Mound Plant (184), INEL (185), and LOS Alamos National Laboratory (LANL) (186), are contaminated with plutonium, americium, and other transuranic elements. Proposed guidelines for transuranics in soil were issued by EPA in 1979 and then withdrawn. EPA now estimates that it will be 5 to 10 years before new guidelines are finalized (187).

Preliminary analyses indicate that surface water sediments have been extensively contaminated with radioactive materials both within weapons sites and off-site (see app. A). Methods for risk assessment of contaminated sediments and remediation practices for this type of pollution are especially primitive.

Regulation of Off-Site Radiation

DOE's authority to implement and enforce its own standards governing off-site radiation doses to the general public is an unusual feature of the U.S. regulatory system and has led to significant public controversy. As authorized by the Atomic Energy Act of 1954, as amended,¹⁴ DOE is responsible for implementing and enforcing all regulations governing the monitoring and control of radionuclides released by DOE operations. Exceptions to DOE's authority to “self-regulate” radiation releases include EPA's authority to set release standards for airborne radionuclides released beyond the fence line of DOE facilities and to implement and enforce such standards under the Clean Air Act,¹⁵ and EPA's authority to regulate discharges into water systems

¹¹42 U.S.C.A. §§6904 (i)(6)(A), (F) (West Supp.1990).

¹²EPA defines operable units as “discrete part(s) of the entire response action that decrease a release, threat of release, or pathway of exposure” (Superfund, Emergency Planning, and Community Right-to-Know Programs, 40 CFR §300.6 (1989)).

¹³Information about these releases, which spurred the establishment of the Hanford Dose Reconstruction Project, did not result from the CERCLA and RCRA investigations in progress at Hanford; rather, it was discovered by a citizens' group reviewing DOE documents obtained under a Freedom of Information Act request.

¹⁴42 U.S.C. §2011-2296 (1982 & Supp. IV 1986).

¹⁵33 U.S.C.A. §1251-1376 (West 1983 & Supp.1990).

under the Clean Water Act.¹⁶ Off-site releases of radioactivity from DOE facilities are also subject to the Safe Drinking Water Act.¹⁷ In general, DOE orders, the internal system of regulation by which DOE promulgates radiation standards governing allowable exposures to workers and to the general public, specify radiation standards that are equivalent to those promulgated by the Nuclear Regulatory Commission and the EPA regulating radiation releases from non-DOE facilities.

It is a fundamental premise of radiation protection that all exposure to radiation should be limited to levels "as low as reasonably achievable" (ALARA). The ALARA principle is joined to another axiom of radiation safety that states, "Each man-made contribution to population exposure [to radiation] should be justified by its benefits" (188). The exact levels of radiation dose that are considered 'safe,' acceptable, or justifiable have undergone successive revisions as scientific understanding of radiation effects grows more sophisticated (see box 3-E). Almost all of these revisions, including the most recent recommendations of the International Commission on Radiation Protection (ICRP), have lowered permissible radiation doses.

Both EPA and DOE have been slow to adopt revised radiation standards. The guidance that governs allowable exposure of workers and the public to radiation released by DOE operations was first promulgated in 1960.¹⁸ In 1987, EPA reduced allowable occupational exposure to radiation,¹⁹ 10 years after ICRP recommended such reductions (189). To implement the EPA guidance, in 1988 DOE issued Order 5480.11 mandating tightened restrictions on allowable occupational radiation doses. The levels of exposure permitted for the general public as a result of DOE operations were updated by DOE in May 1990 and reduced to the levels suggested by the 1977 ICRP guidelines.

ICRP recently announced that it will lower the recommended radiation exposure levels for workers

and medical personnel still further, from the annual limit of 5 rems recommended in 1977 to 2 rems (190, 191).²⁰ These lower limits are based on findings published in 1989 by the National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR V) indicating that the risk of cancer from exposure to low doses of ionizing radiation is higher than previously believed (192, 193). DOE has convened two panels to review the implication of BEIR V for DOE radiation guidelines, but has not issued any new orders. DOE officials believe that radiation limits set by previous DOE orders were sufficiently low that they will be unaffected by BEIR V findings (194).²¹

DOE maintains that, in the recent past, radioactive emissions from its operations have seldom, if ever, subjected off-site populations to doses approaching the recommended limits. Radiation standards governing exposure of the general population are based on estimates of received radiation doses. There are two practical ways of determining such dosages (196). One is to create computer models of off-site radiation doses that use approved models of air pathways and data that describe the amounts of radiation released from a discharge point, the distance to human populations, local weather conditions, and so forth, to estimate the radiation doses that would be experienced by the average off-site individual or the most exposed individual. The second method incorporates actual measurements of the amount of radiation present in the air or water at monitoring stations representative of local residences or point of use into calculations of individual radiation doses.

A review of the environmental safety and health practices of six weapons facilities audited by Tiger Teams through December 1989 revealed many problems with DOE's radioactive monitoring practices and dose assessment methods. Air sampling techniques were "inadequate" at 83 percent of the facilities assessed; 67 percent of the sites visited

¹⁶42 U.S.C.A. §7401-7626 (West 1983 & Supp.1990).

¹⁷42 U.S.C.A. §300f-j (West 1982 & Supp. 1983-1989).

¹⁸Federal Radiation Council, Radiation Protection Guidance for Federal Agencies, 25 Fed. Reg.4402 (1960).

¹⁹Radiation Protection Guidance for Federal Agencies for Occupational Exposure; Approval of Environmental Protection Agency Recommendations, 52 Fed. Reg. 2822 (1987).

²⁰Rem (rads equivalent man) is a unit of dose equivalent that includes conversion factors to account for the different biological effectiveness of different types of radiation.

²¹Some DOE contractors have independently established occupational radiation exposure levels that are lower than those permitted by DOE orders (195).

Box 3-E—Scientific Controversy Over Low-Dose Radiation Effects

It is well established that high doses of ionizing radiation cause cancer. Indeed, more scientific research has been devoted to understanding radiation than to any other known human carcinogen. Yet, questions about the human health effects caused by low doses of radiation (less than 10 rem) are extremely controversial. The problem is that to discern the true effects of radiation at low doses, very large populations must be studied and years or decades must pass from the time of initial radiation exposure until a cancer (the usual health outcome investigated) is detected. The difficulties of following large numbers of people over long periods and of accurately accounting for individual radiation doses, cancer deaths, and risk factors other than radiation exposure, are obvious, and leave much room for uncertainty.

In addition to these logistical problems, scientists must contend with conflicting ideas about how observations of high-dose radiation effects should be incorporated into the mathematical models used to predict low-dose effects. Although the choice of different mathematical models hinges on arcane issues in biostatistics and molecular biology, the risk estimates produced by such models have important implications for radiation protection policies. For example, depending on whether a quadratic or linear dose-response model is used, the interpretation of the excess cancer risk resulting from exposure to 1 rad varies by two orders of magnitude.

The National Academy of Sciences convened a series of expert committees to advise the U.S. Government on the health effects of radiation exposures. The BEIR Reports dealing with penetrating radiation¹ studied the health effects (cancer deaths, birth defects) among groups who had received relatively high doses of radiation such as the Japanese atomic bomb survivors and groups of patients who had received radiation for medical purposes. The committees then applied dose-response models to these findings to predict estimates of the health risks associated with low-dose radiation exposures.

The BEIR estimates of cancer risk have undergone successive revisions as the Hiroshima and Nagasaki survivors age and the available database and records of cancer deaths become more extensive. The BEIR V estimates for fatal cancer risks are three to four times greater than the highest estimates reported in the 1979 BEIR report. BEIR V predicts that a single radiation exposure of 0.1 Sievert (10 rem) would result in 800 extra fatal cancers occurring over the remaining lifetime of 100,000 exposed people.³⁴ The confidence intervals associated with the predicted point estimates are wide; nonetheless, the increase of the estimates of cancer risks associated with low-level radiation exposures calculated by successive BEIR committees illustrates the tentative nature of even the most authoritative analyses of low-level radiation effects. All BEIR reports have noted that the data cannot exclude the possibility that there may be *no risks* from low doses,

Another recent investigation of low-dose radiation effects has attracted much interest. This was a peer-reviewed study reporting an association between the risk of childhood cancer and a father's exposure to low-dose radiation among people living near the Sellafield nuclear reprocessing plant in Britain.⁵⁶ The observed association between fathers' exposure to low radiation doses (10 to 100 mSv or 10 to 100 rems) in the 6 months preceding birth and risk of leukemia among their offspring is not predicted by any previously identified dose-response data and was quite unexpected. The number of cases studied was small, which means it is possible that the findings occurred by chance rather than as a causal result of parental radiation exposure. The association

¹B. Mo&u, "Cancer and Leukemia Risks After Low Level Radiation- Controversy, Facts, and Future," *Medical Oncology and Tumor Pharmacotherapy*, vol. 4, No. 3/4, p. 452, 1987.

²BEIR Reports I, II, III and V all focus on the human health effects of external or 'penetrating' radiation, such as that produced by x-rays, gamma rays, and neutrons. BEIR III reviewed the data on the effects of internal radiation, principally radon, an alpha-emitter encountered by uranium miners.

³National Research Council, committee on the Biological Effects of Ionizing Radiations, *Health Effects of Exposure to Low Levels of Ionizing Radiation*, BEIR V (Washington, DC: National Academy Press, 1989), p. 162.

⁴The views of scientists on the BEIR III Committee were so divided that a minority report was appended. A minority of the BEIR III committee believed the data favored cancer risk estimates that were higher than those advocated by the majority. These higher, minority-supported estimates, which were denounced by some as alarmist at the time, are in line with BEIR V's results.

⁵M. Gardner, M. Snee, A. Hall, C. Powell, S. Dowries, and J. Terrell, "Results of Case-Control Study of Leukemia and Lymphoma Among Young People Near Sellafield Nuclear Plant in West Cumbria," *British Medical Journal*, vol. 300, Feb. 17, 1990, pp. 423-429.

⁶M. Gardner, M. Snee, A. Hall, C. Powell, S. Dowries, and J. Terrell, "Methods and Basic Data of Case-Control Study of Leukemia and Lymphoma Among Young People Near Sellafield Nuclear Plant in West Cumbria," *British Medical Journal*, vol. 300, Feb. 17, 1990, pp. 429-434.

Box 3-E—Scientific Controversy Over Low-Dose Radiation Effects—Continued

was statistically significant however, and the risk of childhood leukemia increased as the father's radiation dose increased, factors that argue against a chance association. Additional studies will be required to determine if as-yet unidentified factors, such as occupational exposure to genotoxic chemicals or exposure to viruses, might provide alternative explanations for the association.⁷

The Sellafield findings raised sharp questions about how much remains to be learned about the health effects of radiation.^{8,9} One response has been a study sponsored by the National Cancer Institute (NCI) that compares cancer death rates among populations living in counties adjacent to nuclear powerplants and DOE nuclear weapons sites to cancer mortality rates among people residing in counties that are not near nuclear facilities.¹⁰ The study also compared cancer mortality rates in the study counties prior to the installation of the nuclear facility to rates some years after operations began. No significant patterns of excess cancer mortality among the study counties was observed.¹¹

As the study's reviewers note however, the NCI study has a number of limitations. The large size of the populations investigated means that relatively few individuals in a study county may actually have lived near a nuclear facility. Small effects among these individuals may have been obscured by dilution of the study counties with people who did not reside near a facility. Also, data on cancer incidence, which are more sensitive to possible increases in cancer rates than are mortality data, were available for only four facilities, none of which were DOE installations.¹² It is difficult to make much of comparisons of cancer mortality rates before and after DOE operations began, since in many cases the weapons facilities were built before accurate records of cancer death rates were kept.¹³

⁷G. Anderson, "Leukemia Linked to Fathers' Radiation," *Nature*, vol. 343, 1990, p. 679.

⁸V. Beral, "Leukemia and Nuclear Installations" (editorial), *British Medical Journal*, vol. 300, Feb. 17, 1990, pp. 411-412.

⁹H.J. Evans, "Leukemia and Radiation," *Nature*, vol. 345, May 3, 1990, pp. 16-17.

¹⁰S. Jablon, H. Zdenek, J. Boice, and B. Stem, *Cancer Populations Living Near Nuclear Facilities, Volume 1: Report and Summary*, National Institutes of Health Pub. No. 90-874 (Washington, DC: U.S. Government Printing Office, July 1990).

¹¹*Ibid.*, p. 4.

¹²*Ibid.*, p. xii.

¹³*Ibid.*, pp. 56-62.

demonstrated deficiencies in effluent source monitoring; and 67 percent of the facilities had deficiencies in the meteorological monitoring programs or data utilized in dose assessment calculations (197). The Rocky Flats Plant, the Y-12 Plant at Oak Ridge, and the Mound Plant were found to have "deficiencies with the pathway analyses, documentation, and/or environmental monitoring in support of dose assessment methodologies" (198). Scientists independent of DOE have also complained about similar shortcomings in radioactive release data at Rocky Flats and Fernald (199, 200). Shortages in personnel trained in radiation measurements and health physics were found at several sites.

Summary: Limitations of Chemical- and Media-Specific Regulations

In sum, the contamination at DOE nuclear weapons sites is characterized by many features that current chemical- and media-specific regulations address least successfully and for which existing

laws may be least protective. A relatively small number of environmental contaminants are regulated by chemical-specific or media-specific standards. Many situations throughout the Weapons Complex are not covered by such standards, including historic releases of contaminants that cannot be detected by current environmental samples and contaminant ion of soil or sediments by radionuclides.

Furthermore, even when chemical-specific or media-specific standards do exist, their application to contamination at the Weapons Complex may not ensure adequate protection because of the complexities of multiple contaminants in certain media and multiple human exposure routes. Finally, outdated DOE radiation standards and the tradition of DOE self-regulation make it difficult to assure communities that compliance with existing standards will result in an appropriately or adequately safe environment.

Box 3-F-Quantitative Risk Assessments

Quantitative risk assessments typically consist of at least four steps:

1. hazard identification,
2. dose-response assessment,
3. exposure assessment, and
4. risk characterization.

Hazard identification is the determination of whether a substance causes adverse biological effects. The Environmental Protection Agency (EPA) uses a "weight of evidence" approach in judging the hazard potential of a substance. All available scientific evidence is reviewed and evaluated for accuracy, applicability, etc., so that the most suitable data are used to assess the nature of the hazard posed by a chemical.¹ The effects of substances that are structurally similar may be considered. Most available toxicological information comes from animal experiments and pertains to cancer-causing effects. In the absence of a compelling reason to evaluate the hazards of a particular mixture, only individual contaminants are considered.² If a substance is determined to be nonhazardous, or no data are available indicating that the substance is hazardous, the risk assessment ends here.

At Superfund sites, "indicator chemicals" are selected from lists of contaminants revealed by preliminary analysis to be present at the site. Indicator chemicals are those believed to pose the greatest health hazard at a site; they are chosen on the basis of toxicity (i.e., hazard identification), concentration and amount, mobility, and persistence in the environment. At more complex sites a proportionally larger number of indicator chemicals should be examined.³

Dose-response assessments specify the quantitative relationship between a given dose (absorbed amount) of a substance and the severity or probability of an adverse effect; they provide a measure of a substance's potency. Selection of a dose-response relationship can be controversial, in part because the interpretation of most available data requires extrapolation across several categories, usually including species, sex, age, dose range, exposure pattern, and absorption routes. Human data derived from epidemiological studies are allotted more weight when available, but most epidemiological studies focus on occupational exposures and situations that are not necessarily representative of environmental exposures in the general population. Deriving dose-response relationships of low dosages of potentially carcinogenic substances may be especially controversial because available data can often be reconciled with more than one mathematical dose-response model.⁵

Exposure assessments are estimates of the degree of individual exposure to a given substance and the number of people exposed. The determination of exposure is crucial in conducting quantitative risk assessments (QRAs). If the actual or potential exposure is not recognized, either because of failure to identify significant environmental transport pathways and exposure routes or because of inaccurate estimation of the number of people exposed or exposure levels, the resulting risk estimate will be misleading.

Direct measurements of human exposure (e.g., analyses of blood or urine samples that indicate individual exposure to a substance) are rarely used in QRAs, and most such measures remain research tools. Instead, QRAs typically use indirect measures of human exposure, such as computer models based on environmental monitoring data, to project estimates of individual dose. For example, some measure (mean, median, or upper confidence limit levels) of ambient contaminant concentrations may be multiplied by standard intake values (estimates of how much air one breathes, water one drinks, etc., over a 70-year lifetime or other appropriate exposure duration) to produce a dose estimate. The estimated dose is then related to the relevant legal standards or to exposure levels that have been predicted to pose no more than "acceptable" levels of risk for the health effect at issue.

¹U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, *Risk Assessment Guidance for Superfund, Human Health Evaluation Manual Part A*, September 1989, pp. 7-1-7-20.

²Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 *Fed. Reg.* 34014 (1986).

³C. Zamuda, "Superfund Risk Assessments: The process and Past Experience at Uncontrolled Hazardous Waste Sites," *Risk Assessment of Environmental and Human Health Hazards: A Textbook of Case Studies*, B. Paustenbach (ed.) (New York, NY: John Wiley & Sons, 1989), pp. 273-280.

⁴B. Paustenbach, "Health Risk Assessments: Opportunities and Pitfalls," *Columbia Journal of Environmental Law*, vol. 14, 1989, pp. 365-379.

⁵*Ibid.*, pp. 391-393.

DESCRIPTION AND EVALUATION OF SITE-SPECIFIC HEALTH EVALUATIONS REQUIRED BY REGULATIONS AND INTERAGENCY AGREEMENTS

Conditions at a toxic waste site may not be adequately addressed by existing chemical- and media-specific standards. For this reason, in addition to complying with ARARs, each site on the National Priorities List (NPL) is required to undergo quantitative risk assessment. Quantitative risk assessment (QRA) is a methodology for evaluating the health implications of environmental contamination in the face of incomplete knowledge of the molecular mechanisms that lead to disease (see box 3-B).

QRAs attempt to quantify the hazard associated with a particular pollutant under specific conditions of exposure. The product of a risk assessment is a "risk estimate"—a calculation that relates a contaminant's chemical characteristics, toxicological behavior, and conditions of exposure to the probable incidence of the adverse effect under consideration (usually cancer) in a given population (201) (see box 3-F).

Quantitative Risk Assessments Required by CERCLA

Quantitative risk assessments of conditions at weapons sites will be conducted by DOE, or DOE contractors and subcontractors, and reviewed by EPA. The baseline risk assessment describes the site "as is," before any remediation work is begun, and is completed as part of the remedial investigation/feasibility study (RI/FS) stipulated by CERCLA.²² Refinements of the baseline analysis and additional risk assessments are incorporated into the final Record of Decision (ROD),²³ which documents the findings of the RI/FS and speciesproposed cleanup actions (202).

The health risks that are projected to be associated with any proposed cleanup remedy, as calculated by quantitative risk assessment methods, are also pre-

sented in the ROD. Proposed cleanup strategies must yield "acceptable" risk estimates to win approval from regulators. Thus, the central purpose of CERCLA quantitative risk assessments is to assist cleanup managers in choosing among various cleanup strategies.

QRAs provide a useful format for performing a disciplined evaluation of some potential health impacts associated with environmental contaminants. They have proved valuable for formulating policy in the face of limited technical information. The quantitative risk assessment process under CERCLA is also associated with technical and procedural problems, however.

Technical Problems Associated With Quantitative Risk Assessments

The technical limitations of quantitative risk assessments stem from fundamental uncertainties in the scientific understanding of how environmental contaminants affect human health. Attempts to quantify the health risks associated with exposure to a chemical or a radionuclide must grapple with many uncertainties. Limited available data must be extrapolated across dose ranges, exposure routes, age, sex, and—in the case of animal data—species, to be applied to specific situations of human exposure. As discussed earlier, only a small proportion of the chemicals in use have been tested for toxic effects, and most of the available information pertains to a substance's cancer-causing potential. The effects of a substance on neurological, immunological, or reproductive functions are largely uninvestigated, as are the consequences of low-dose, chronic exposures.

EPA has attempted to deal with the pervasive uncertainties in the toxicological knowledge base by standardizing the assessment of the hazard associated with a certain chemical (203 -205).X At Superfund sites, "indicator chemicals" that are especially pervasive, persistent, or dangerous are selected from among all the toxic chemicals discovered at the site and subjected to detailed analysis. The selection of which and how many chemicals at a site should

²²42 U.S.C.A. §9620(e)(1) (West Supp. 1990).

²³42 U. S.C.A. §§9621(a)-(f) (West Supp. 1990).

²⁴Radionuclides are, of course, chemicals. In some cases, the major toxic effects of a substance are a result of its radioactive properties. With other radionuclides, however, chemical toxicity causes the most damage. For example, the radioactivity of natural uranium is very low and does not produce appreciable radiation damage when ingested or inhaled at dosages below the Annual Limit on Intake. However, at these doses the chemical toxicity of uranium can cause kidney damage (206, 207).

Such exposure models may or may not be validated and can vary widely in complexity.⁶ At Superfund sites, because of the difficulties involved in identifying and mapping contaminants at a site, exposure assessments as currently conducted may be one of the risk assessment components most vulnerable to error.

Risk characterization is the process wherein all the foregoing pieces are incorporated into a mathematical model that represents the probable risks of exposure to a given population for which a risk estimate is being calculated. Risk characterization is clearly dependent on the accuracy of its components: the applied hazard information, dose-response relationships, and exposure estimates.

Risk characterization also requires judgments about how to handle uncertainties in the underlying data, how to select appropriate dose-response and exposure estimates from (often incomplete, ambiguous, or conflicting) available data,⁷ how to assemble this information into an overall model, and how to present the results of the assessment and its attendant uncertainty to the risk manager.

⁶A. Finkel, "Is Risk Assessment Really Too Conservative? Revising the Revisionists," *Columbia Journal of Environmental Law*, vol. 14, no. 2, 1989, p. 430.

⁷q-o-tt= o,h,-ti-tio~ Mm for &sessm@t of ~~, Natio~ R~~~hco~Cil, RiskAssess~n# in the *Federal Government: Managing the Process* (Washington IX: National Academy Press, 1983), p. 36.

serve as indicator chemicals is to some degree prescribed by EPA but is also a matter of judgment (208).

Many steps in the risk assessment process require the risk assessor to make judgments (209, 210). EPA has recommended algorithms that can supply some consistency in determining how such judgments or "inference points" might be determined. For example, EPA has developed computerized data sources describing the toxic effects and potency factors of chemicals, along with tables that assist the risk assessor in applying this information to the conditions at a specific site (211).

Risk assessors are not legally required to utilize EPA's recommended inference assumptions (212). The Risk Assessment Guidance that spells out EPA's preferred risk assessment algorithms does not have the force of law; such algorithms are meant to be flexible enough to accommodate the specific features and circumstances of a site and are not intended to serve as a "cookbook" of risk assessment techniques (213). However, DOE has not established any directives to ensure that DOE contractors and subcontractors follow consistent procedures for collecting environmental samples, analyzing data, or choosing among inference assumptions as risk assessments are developed throughout the Weapons Complex. Therefore, it is likely to be difficult, if not impossible, to compare risk estimates either within or among sites.

Although determination of the *hazard* term of a risk assessment has become increasingly standard-

ized as a result of EPA efforts, determination of the *exposure* term of CERCLA risk assessments is less clearly spelled out by EPA guidelines (214). Consequently, there is more variability in the methods used to assess exposure at Superfund sites. Estimates of how many people are exposed to toxic materials, and in what doses, depend both on a knowledge of environmental transport pathways and on approximations of how much of an environmental toxicant an individual might actually absorb from contact with contaminated air, water, soil, or vegetation.

The results of environmental sampling are clearly crucial to an accurate understanding of where contaminants have traveled in the environment. Characterization of environmental contamination is a difficult task with many elements of uncertainty (see app. B). If sampling strategies fail to detect a particular contaminant or if computer models of environmental transport pathways do not accurately map the presence and concentration of a contaminant, the exposure estimates derived from such results will be inaccurate.

Variability in the age and habits of individuals can also greatly affect exposure. Children, for example, typically have more contact with soil than do adults (215). People who spend a great deal of time outdoors or who use polluted waterways for recreation may have very different exposures compared with other members of a community. It is, therefore, important to obtain updated information describing land use and population characteristics in communities surrounding a waste site.

Any quantitative risk assessment, no matter how competently and carefully performed, contains many areas of uncertainty (216). It has been argued that EPA risk estimates are expressed in terms that imply more precision than is warranted. Some critics have urged EPA to institute formal processes for specifying and dealing with the uncertainty in QRAs and to publish risk estimates giving the entire range of values that are consistent with the observed and calculated features of a situation (217). Thus, rather than portraying risk as a single number or “point estimate” that gives an unwarranted impression of precision, or presenting very broad and unhelpful ranges of possible estimates (e.g., a risk between 0 and 100), risk assessors could present the range of calculated estimates along with an indication of the probability that the numbers in the range are correct (218).

Formal uncertainty analysis may produce a more detailed or realistic appraisal of some risks associated with a situation, but from the viewpoint of policymakers, this strategy also has problems. Uncertainty analysis introduces another layer of abstraction into a process that is already quite technical and difficult for risk managers to interpret. Concern also exists that the additional complexities of uncertainty analysis would increase public skepticism about risk assessment methods (219).

Furthermore, formal analysis does not alter the basic uncertainties embedded in quantitative risk assessments of environmental toxicants (220). Quantitative risk assessments are largely limited to the estimation of those health outcomes for which toxicological data are available—principally acute, high-dose, health effects and cancer risks. A QRA is inherently incapable of discovering health effects that have not yet been linked to a particular exposure or that are not predicted by available dose-response data.

Risk estimates are “probabilistic summaries of unknowable future events” (221) and it is difficult to test or verify their validity. EPA risk estimates, generated not for Superfund sites but for more generic regulatory policies, have been criticized for both over- and under-estimating actual risk (222, 223). Some critics contend that risk-based environmental regulations consistently overestimate “real risk” by employing deliberately conservative, health-protective assumptions throughout the assessment process (224-226). Others dispute this view and

maintain that many “conservative” assumptions may overestimate the actual risk (227-230).

Procedural Problems Associated With Quantitative Risk Assessments

CERCLA risk assessments take a long time to carry out. Review of the 1988 list of Records of Decision completed at Superfund sites revealed that 38 to 42 months elapse from the initial preliminary assessment phase of CERCLA until a ROD is complete (231). These long timeframes result partly from the technical challenges involved in characterizing a large or complex site, and partly from the slow pace of the regulatory review process. Although EPA and the States may have access to site characterization data and the baseline risk assessment as it is developed, years can pass before environmental monitoring results or completed risk estimates are released to the public.

Risk assessors are rarely involved in designing the approach to environmental sampling and site characterization (232). As a result, it may be necessary for engineers to collect additional environmental samples or revise models of transport pathways to provide data that are needed for the risk assessment but were not acquired during the initial remedial investigation. In some cases, environmental engineers may expend great effort and money characterizing details of a site that have little or no bearing on human health risks.

EPA has recently urged site managers to involve risk assessors in the early stages of environmental characterization and to gather data with clear questions and information requirements in mind (233). In practice, however, engineers with little or no health background control the collection of environmental samples, and other experts, who may also lack expertise in toxicology or environmental health, develop the environmental transport models.

DOE has advocated that “risk-based cleanup priorities” be used to determine cleanup goals (234). This is a reasonable objective, but it fails to acknowledge the technical uncertainties and practical limitations of risk assessment techniques. In some instances, the available data may be too sparse to conduct a meaningful risk estimate. In other situations where risk assessment techniques can be reasonably applied, risk estimates do not automatically translate into coherent policies or explicit management decisions. For example, although risk

analyses have been advocated as a means of devising a hierarchy of health-based cleanup priorities, it is not generally true that quantitative risk analyses are well-suited for prioritizing risks. When individual risk estimates are highly uncertain, comparing risks can be very misleading (235).

Disputes about the complexities and uncertainties of site characterization have long been sources of controversy at non-Federal facility Superfund sites. Different stakeholders, some interested in minimizing uncertainty about possible health effects and others concerned about holding down costs, have different views about how much information is needed to adequately characterize a site and formulate a cleanup plan (236). Questions about "how clean is clean enough?" to protect public health are similarly problematic. The basic difficulty is that scientific understanding of the health effects of environmental contamination is very limited. As the National Research Council Committee on Risk Assessment in the Federal Government has pointed out, there is no ready solution to this problem (237).

EPA recommends early and ongoing community involvement in the QRA process (238). Residents' observations and suspicions of possible toxic exposures or health outcomes could provide valuable clues to risk assessors. Early and ongoing interactions among communities, regulators, and potentially responsible parties (PRPs) might enhance community appreciation of the purposes and limitations of QRAs, and improve acceptance of proposed cleanup remedies.

In practice, however, community members are seldom consulted during the risk assessment process. Instead, final risk estimates are presented with accompanying technical analysis and a chosen remediation plan. Affected communities often interpret such risk estimates as justifications of the cleanup remedy preferred by the PRP (239). Private citizens and community groups typically lack the time and expertise needed to critically review a complicated risk analysis. Also, people often have difficulty relating mathematical functions to concerns about the well-being of themselves or their families. Residents may not be reassured to learn that the lifetime chance of dying of cancer as a result of contamination of their neighborhood is only one in 10,000.

CERCLA risk assessments sometimes fail to address specific issues of concern to local communities. For example, residents may be worried about whether their children's learning disabilities are due to pollution, whereas the QRA focuses on evaluating the risk of cancer deaths. Communities left to worry for years while a QRA is completed may become disappointed and angry when the long-awaited risk estimates fail to resolve their concerns.

Finally, although QRAs will be conducted at all weapons sites on the NPL, those facilities that do not contain Superfund sites are not legally required to undergo risk assessment. Thus, some potentially important sources of toxic contaminants will not be subjected to QRAs. Corrective action measures at those RCRA sites that have released toxic materials must be evaluated in light of the potential health risks they are designed to mitigate. However, EPA has not issued agencywide guidelines stipulating how such risks should be assessed (240). Consequently, "risk assessment" at RCRA sites varies among EPA regions but, when done, is generally far less detailed than Superfund QRA methods.

Site-Specific Health Assessments Conducted by the Agency for Toxic Substances and Disease Registry

Statutory Authority

The Agency for Toxic Substances and Disease Registry (ATSDR) was established by CERCLA in 1984 and began operating with the passage of the 1986 Superfund Amendments and Reauthorization Act (SARA).²⁵ Along with the National Institute for Environmental Health Sciences (NIEHS), which conducts basic research into the biological mechanisms of environmental hazards, and the National Institute for Occupational Safety and Health (NIOSH), which studies risks faced by workers at hazardous waste sites, ATSDR is designed to be one of the Nation's principal agencies for the study of human health effects resulting from exposure to environmental contamination.

ATSDR is required by statute to perform a health assessment on the potential public health impact of every Superfund site within 1 year of a site's being

²⁵Pub. L. No. 99-499, 100 Stat. 1615 (1980) (codified in scattered sections of the I.R.C. and 10, 19, 33 and 42 U.S.C.).

proposed for inclusion on the NPL.²⁶ If the available site information is insufficient to support a complete health assessment in that timeframe, a preliminary health assessment may be issued, with subsequent documents adding refinements and details as data become available. A completed health assessment may, therefore, be a series of documents or reports released as information is generated and conclusions or recommendations are modified (241).

Operators of RCRA sites are required to submit information to EPA (or to the State in the case of State sponsorship) describing any “reasonably foreseeable potential release” that might result from routine operations or accidents. Under RCRA, documentation must address the nature and magnitude of possible releases, as well as describe potential pathways of human exposure.²⁷ If EPA or the responsible State determines that a RCRA site poses a “substantial potential risk to human health,” ATSDR may be requested to perform a health assessment. RCRA goes on to say that “if funds are provided in connection with such request, the Administrator of ATSDR shall conduct such health assessment.” Federal facilities are required to pay their own CERCLA costs. Presumably, DOE would be the funding source for ATSDR health assessments at RCRA facilities. It is unclear whether an ATSDR health assessment would be performed at RCRA sites in the Weapons Complex if such funds were not made available.

ATSDR’s authority and responsibility at RCRA sites within the Weapons Complex may be further expanded by two provisions of CERCLA. Under CERCLA, ATSDR can consider health risks to populations residing near Superfund sites that arise from sources other than the facility in question.²⁸ Thus, at weapons facilities that contain both CERCLA and RCRA sites, ATSDR could invoke its CERCLA authority to perform health assessments at RCRA units as well.

Furthermore, CERCLA requires ATSDR to respond to petitions from Congress or individual citizens requesting evaluation of any exposure to toxic substances for which the probable source of exposure is an environmental release.²⁹ Thus, ATSDR

health assessments could be conducted at weapons facilities that do not contain Superfund sites if local citizens or Congress requests such investigations.

Health Assessment Methods

ATSDR health assessments have three purposes (242, 243):

1. to evaluate the public health implications of a site,
2. to address these implications by identifying the need for any additional health or environmental studies, and
3. to identify actions necessary to mitigate or prevent adverse health effects and to recommend that EPA take the steps required to carry out such actions (e.g., provision of alternate water supplies, relocation of individuals).

The basic approach to be used in conducting health assessments at Superfund sites is outlined in the ATSDR Draft Health Assessment Guidance (244). The health assessment is based on environmental data, health outcome data, and community concerns. Environmental data include those descriptions of contaminants and migration pathways developed by EPA in the course of its own preliminary assessment and remedial investigation, as well as demographic data pertinent to the site. Health outcome data may include medical records; morbidity and mortality figures obtained from local, State, or National databases; tumor and disease registries; birth statistics; and surveillance data. Community concerns are those site-specific health issues raised by local residents and identified in public meetings, during “house calls,” and from the recommendations of State or local health officials (245).

If the results of a health assessment point to the need for additional studies, ATSDR has authority to exercise the full scope of environmental health investigative methodologies at Superfund sites, including the administration of symptom questionnaires and health surveys, the establishment of health surveillance and exposure registries, and the design and execution of pilot studies and full-scale epidemiological investigations (see box 3-B). ATSDR employs the range of professionals and technical

²⁶CERCLA Section 101, 42 U.S.C.A. §6904(i)(6)(A) (West Supp. 1990).

²⁷42 U.S.C.A. §§6939a(a)-(b) (West Supp. 1990).

²⁸CERCLA Section 101; 42 U.S.C.A. §§6904(i)(6)(F)-(G) (West Supp. 1990).

²⁹CERCLA Section 101; 42 U.S.C.A. §6904(i)(6)(B) (West Supp. 1990).

experts needed to carry out comprehensive environmental health assessments, including hydrogeologists, toxicologists, physicians, epidemiologists, biostatisticians, and health physicists.

ATSDR could, for example, carry out pilot studies to test the need for, or feasibility of, more elaborate health investigations. Such studies might examine evidence of exposure to hazardous materials among individuals. Unlike EPA and site contractors conducting exposure assessments under the QRA provisions of CERCLA, ATSDR has on occasion used direct measures, such as blood and urine assays, to detect individual exposure to environmental contaminants (246). When available, such direct methods are more reliable and specific than indirect exposure measures such as computer models. Direct exposure measures can also be used to help validate the computer models used in QRAs at a site.

In addition to conducting pilot studies, ATSDR can subject sites to more complex epidemiological investigations, including case-control studies, cohort studies, or cross-sectional studies. In some cases, ATSDR staff designs and carries out such investigations. CERCLA also allows ATSDR to enter into cooperative agreements with State health departments and State universities in conducting such studies.

When exposure to potentially hazardous materials has occurred but the severity or nature of resulting health impacts is unclear, ATSDR can establish exposure registries to track exposed individuals over time and arrange for periodic medical surveillance, evaluation, and documentation of health status. In this way, scientific understanding of the consequences of such exposure is enhanced, and exposed populations have concrete evidence that their concerns are being acknowledged and their health monitored. ATSDR has established two exposure registries to date, one for individuals exposed to dioxin and the other for populations exposed to the solvent trichlorethylene (247).

Evaluation of Health Assessment Methods

The scope of health issues that ATSDR may consider is broader than that required of EPA or of potentially responsible parties at Superfund sites. CERCLA-mandated quantitative risk assessments deal only with toxic chemicals, whereas ATSDR health assessments can consider both chemical and physical hazards. Thus, ATSDR can recommend, for

example, that potentially explosive materials be immediately removed from a site, that a dangerous site be fenced off, or that open pits be covered. ATSDR may also consider all past aspects of a site's operations, including historical releases, if they are believed to impact on human health. QIL4s consider only present and future risks posed by the site, that is, what toxic chemicals are in the environment now and where they are moving (248).

A major strength of ATSDR'S policy is the emphasis placed on establishing effective and ongoing communication with affected communities. The Draft Health Assessment Guidance states that ATSDR will deliberately seek out members of communities neighboring Superfund sites and solicit their concerns and ideas in public meetings. Specific health concerns voiced by residents are to be taken seriously and addressed without exception. Responses to such concerns may vary from verbal reassurances that no cause for alarm exists to full-scale health investigations where warranted (249).

Such a commitment to early and ongoing public participation in health studies reflects the strongly held view of public health officials interviewed by OTA who maintain that it is essential to apprise communities of the purposes, nature, and limitations of all health studies planned or underway therein (250-253). According to health officials and researchers experienced in investigating the health effects of environmental exposures, the most serious barrier to successfully communicating the import of health studies to the public is not the lay public's lack of scientific sophistication. If the technical details are described competently and are regarded as important, people will take the necessary pains to understand them. William Ruckelshaus, who twice served as EPA Administrator, has also stated his belief that "it is possible for people subject to toxic risk to think rationally about it" (254).

Rather, the most common and often disastrous barrier to communication is the failure of professionals and technical experts to listen to communities, to provide meaningful opportunities for the exchange of information as a study proceeds, and to acknowledge the uncertainties involved in the scientific analysis used to support decisions. These observations echo the findings of the National Research Council Committee on Risk Perception and Communication (255).

Limitations on Health Assessments

In practice, ATSDR's accomplishments are limited by a small staff and inadequate resources. The Agency is small: it consists of about 200 people (256). ATSDR is also new and just beginning to establish itself. ATSDR is part of the Public Health Service in the Department of Health and Human Services; however, it must compete for attention with the CDC, whose director is also the director of ATSDR, although ATSDR is not itself part of CDC. ATSDR obtains its funding from EPA. These convoluted lines of authority create cumbersome bureaucratic procedures.

The 1-year deadline for completion of health assessments was designed to ensure that health issues at Superfund sites are addressed in a timely manner. Although this goal is laudable, the effect of the 1-year deadline has been to force ATSDR to rely on whatever information about the site has already been collected by EPA and is available at the time. In most cases, this information is neither reliably accurate nor comprehensive.

Furthermore, environmental data gathered to inform engineers about needed remediation strategies are not necessarily the same data required for health studies. For example, in some cases, the PRP at a Superfund site may not be motivated to collect environmental monitoring information that suggests a possible public health problem, or the data needed to evaluate proposed remedial activities may not include information about the possible health impacts of past releases. ATSDR can request that EPA or the site contractor collect more detailed information or generate data directed at particular concerns, but such requests are usually not complied with in time for the results to be included in the health assessment.

ATSDR scrambled to meet the regulatory deadline for completing the backlog of health assessments that existed when it came into being: 951 health assessments were prepared within a few months, many by outside contractors (257). The quality of these reports was predictably poor. ATSDR now maintains that its health assessments are subjected to considerable internal oversight and review. The Agency has recently reevaluated its guidelines for performing health assessments and attempted to make the process more rigorous.

Health assessments performed by ATSDR at Federal facilities and other Superfund sites have been criticized as superficial and even misleading (258, 259). The health assessment performed at Colorado's Rocky Mountain Arsenal, an Army facility that is comparable in size and complexity to some of the DOE weapons sites, was criticized for its failure to consider air pathway exposures, the use of inaccurate demographic data, and its reliance on incomplete and preliminary toxicological data (260-262). The Colorado Department of Health, the U.S. Army, and EPA all criticized ATSDR's failure to review more than a small portion of the available site characterization information. The EPA review acknowledged that ATSDR's effort was constrained by limited staff and noted, "Given the size, complexity, national significance and environmental and public health concerns associated with [the site], EPA strongly suggests the application of a much larger ATSDR resource level henceforth. . ." (263).

ATSDR currently lacks the staff necessary to critically evaluate the accuracy and adequacy of environmental characterization data supplied to EPA by site contractors. Resource limitations also prevent the Agency from utilizing teams of experts at a single site. Although ATSDR employs the appropriate range of health professionals and technical experts, in practice its staff is spread too thin to permit in-depth, multidisciplinary examination of conditions and potential health threats at each CERCLA site.

At non-Federal facility Superfund sites, ATSDR has shared or delegated responsibility for conducting health assessments through cooperative agreements with State health departments and State universities (264). These arrangements provide a means for ensuring local input into the assessment process and augmenting the ATSDR staff. Federal authorizing statutes do not permit ATSDR to make use of the resources of private or out-of-state colleges and universities, however. ATSDR has determined that for Superfund sites at Federal facilities, including DOE weapons sites, it will not delegate its authority to conduct health assessments to the States (265). (This decision does not bar cooperative agreements between ATSDR and the States to carry out specific health studies at weapons sites, however.)

DOE/ATSDR Memorandum of Understanding

In the fall of 1990, after more than a year of negotiation, DOE signed a Memorandum of Understanding (MOU) with the Department of Health and Human Services (HHS) (266). This MOU authorizes ATSDR to begin discussions with the seven individual DOE Operations Offices in pursuit of inter-agency agreements that will eventually provide ATSDR with the resources to conduct health assessments at the nuclear weapons sites on the NPL.

Although the MOU represents a significant step forward, much further negotiation remains to be accomplished. ATSDR must now sign IAGs with each of the DOE Operations Offices to specify the procedures DOE will follow in disclosing “all relevant information and data (toxicological, human health and environmental operations data)” concerning each weapons site where a health assessment is planned “or where ATSDR in consultation and cooperation with DOE, determines that other health related activities are needed” (267).

The potentially circumscribed authority given to ATSDR by this MOU may seriously impede its ability to effectively address the major health issues raised by environmental contamination at Weapons Complex sites. The DOE/ATSDR MOU stipulates that all “long-term health-related activities” (i.e., any health studies other than the CERCLA health assessment) will be “provided to” an advisory committee established by HHS as part of the agenda under development for “energy-related analytic epidemiological studies” (268) (see box 3-G). It is unclear, therefore, whether ATSDR, CDC, or nongovernment scientists would design and conduct such studies, or whether ATSDR would require consent from the advisory panel to proceed with investigations deemed necessary.

ATSDR's limited resources are also constraining. An ATSDR internal memorandum notes, “Of all the sites proposed for listing on the NPL, the Federal facilities are among the most complex” (269). Present plans call for the formation of two types of health teams: “one focusing on the health issues and concerns of the communities and their officials,” and the other focusing on environmental contamination and human exposure pathways. Each team would consist of two persons who would spend the equivalent of 1 month visiting a site; meeting with community members, local, State, and health depart-

ment officials, and environmental agencies; reviewing and interpreting available characterization information to determine which sites or parts of sites pose or have posed the greatest threat to human health; and identifying, planning, and executing appropriate DOE followup health studies (270).

ATSDR explicitly acknowledges that this plan is severely circumscribed by limitations of staff and money (271). It is difficult to imagine how such an effort—which is heroic by ATSDR standards—will achieve even modest success. It is doubtful that two people, no matter how expertly trained, can adequately review the situation at a single weapons site and produce even a rough assessment of potential public health impacts, let alone establish contacts with communities, critically evaluate available characterization data, and design future assessment interventions. Such a strategy may identify some glaring problems and information needs but is also likely to produce a spate of superficial assessments that will be of little help in guiding the cleanup and may undermine ATSDR's credibility and future assessment efforts at the site. The prohibition against ATSDR entering into arrangements with private academic institutions is especially constraining because it bars the agency from drawing on the talent and advice of a large and experienced pool of environmental health researchers.

Summary: ATSDR Health Assessments at DOE Weapons Complex Sites

In summary, ATSDR's statutory mandate to investigate the health effects of environmental toxicants makes it the logical Federal agency to carry out site-specific evaluations of possible health impacts of Weapons Complex contamination. On paper, the methodological approaches embraced by ATSDR in investigating environmental health effects are sound. However, ATSDR has yet to accomplish much work at the weapons sites, largely because of staff shortages and delays in completing negotiations between HHS and DOE. Some observers, including university-based environmental health professionals and State health officials, are skeptical that ATSDR, with its limited resources and insecure position within the HHS bureaucracy, can successfully conduct scientifically rigorous and independent health assessments at the weapons sites.

Role of State Health Departments and Federal Centers for Disease Control in Health Assessments

Status of State Health Department Efforts

One remarkable aspect of the DOE cleanup is the limited involvement of State and local public health professionals. Although State health officials are frequently in direct contact with communities potentially affected by the contamination early and over the long term, the ambiguity of their health departments' authority at Federal facilities (272, 273) and the limitations on staff expertise and funding have left many State health departments without a clear role in the cleanup.

Often, State governments are structured so that separate departments preside over health and environmental issues and have little experience in collaboration (274). In many States hosting weapons facilities, departments of the environment have taken the lead role in designing plans for site characterization, remediation, and health assessment; local health officials often have limited knowledge of, or involvement in, the cleanup. In Colorado, where environmental and health protection functions are both part of the Department of Health, health officials have been directly involved in negotiating details of the interagency agreements among the State, EPA, and DOE. Yet, even when health officials are involved in the cleanup, the authority of their departments to enforce State health or safety regulations at Federal facilities has been disputed (275).

The resources available to State regulators vary but are generally modest. Most State health departments are struggling with limited budgets and experiencing problems in attracting strong leadership (276). Many States do not have experts trained or experienced in environmental health or employ only a few such individuals who are responsible for a wide range of projects. In some locations, past deficiencies in the expertise of health officials have left citizens distrustful of State regulators.

All of the involved States are attempting to negotiate agreements with DOE that include funds enabling them to hire more regulators and to cover overhead costs. Colorado and Idaho have signed agreements in principle (AIPs) that require DOE to fund State-sponsored health studies (277-280). The

State of Tennessee is seeking to **negotiate similar assurances** of funding for site-specific health studies, dose reconstruction projects, and birth defects and cancer registries (281, 282).

The Colorado Department of Health was very active in formulating the interagency agreement and the AIP worked out by the State, DOE, and EPA. Activities under the Colorado IAG address the cleanup requirements of RCRA and CERCLA and call for the Governor to appoint independent advisory panels to review the adequacy of DOE's environmental monitoring at Rocky Flats and to design any health studies deemed necessary once preliminary characterization data are available (283).

The Colorado AIP is broader than RCRA or CERCLA in terms of conditions for compliance and envisions health studies including toxicological reviews, dose reconstruction, and risk characterization based on historical data. The proposed studies would be contracted out by the Colorado Department of Health to independent investigators (284). Funding sources for such studies were not identified in the IAG or AIP. It is unclear what will happen to Colorado's plans for independent health studies if Congress fails to appropriate the money necessary for DOE to fulfill all promises made to the State.

Status of Centers for Disease Control Efforts

Several States have turned to experts at the Federal Centers for Disease Control for advice and assistance in assessing possible health consequences of contamination at the weapons sites. Staff members from the CDC Center for Environmental Health and Injury Control (CEHIC) have played central roles in establishing the epidemiological study of thyroid disease that will follow the Hanford Environmental Dose Reconstruction Project. This study will be carried out by independent researchers from the Fred Hutchinson Cancer Center in Seattle, WA, in collaboration with CDC. CEHIC also plans a dose reconstruction of airborne uranium emissions from the Feed Materials Production Center in Fernald, OH (285).

The CEHIC effort at DOE sites is being carried out by a staff of 12 scientists. The success of their efforts thus far and the fact that CEHIC is the only real public health presence at weapons sites have placed them in demand by other States. The Governor of Colorado has requested that CEHIC staff

Box 3-G—Authority Over DOE Health Data

The Department of Energy (DOE) has been engaged in negotiations with the Centers for Disease Control (CDC) to transfer partial responsibility for future epidemiological studies having to do with weapons sites operations to CDC. Such a transfer was recommended in March 1990 by the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) for the U.S. Department of Energy, appointed by Secretary James Watkins. SPEERA was charged with providing an “independent evaluation of the DOE epidemiological program, and the appropriateness, effectiveness, and overall quality of DOE’s epidemiological research abilities.”¹

SPEERA recommended that responsibility for conducting epidemiological investigations of DOE operations be transferred out of the Department after finding that the Department’s role in promoting energy and weapons production represented an “inherent potential conflict of interest between immediate production goals and health and safety goals.”² SPEERA also heard testimony that DOE and its contractors had endeavored to “influence epidemiological findings inappropriately” and had made it difficult for researchers other than DOE’s major long-term contractors to conduct health studies at DOE facilities by avoiding open competition for epidemiologic research projects.³

The SPEERA recommendations, which the Secretary pledged to adopt,⁴ and their codification in institutional arrangements have important implications for health studies related to weapons site cleanup. Open access to records of exposures and health outcomes among DOE employees at the weapons plants may be important in providing clues about what hazardous exposures and health effects should be considered among off-site residents.

Additionally, the institutional recipient of DOE worker data will also be awarded the funding and staff allotments necessary to carry out future analyses on the database. Such resources could create a new center of expertise in radiation-related health issues. Currently, such expertise is restricted to a few government employees scattered throughout several agencies, a situation that is problematic for the evaluation of health effects stemming from contamination at the Weapons Complex.

The institutional embodiment of the SPEERA recommendations will also be a signal of DOE’s new ethic of openness regarding health data. In accord with an out-of-court settlement, DOE recently turned over a portion of the worker data to an independent epidemiologist who has long been critical of DOE contractor analyses of the health effects of radiation exposures among weapons plant employees.⁵ The transfer of responsibilities for “analytical epidemiology” studies to the Department of Health and Human Services (HHS) is seen as the next step in instituting DOE’s “new culture” of openness and is awaited as evidence of DOE’s commitment to environmental, health, and safety issues.

However, the draft Memorandum of Agreement between DOE and HHS indicates that formidable barriers may continue to confront independent researchers who seek access to the DOE occupational health database. Under the proposed conditions, investigators must obtain a formal interagency agreement approved by the Secretary of Health and Human Services and the Secretary of Energy to gain access to the Comprehensive Epidemiological Data Resource (CEDR).⁶

¹U.S. Department of Energy, Secretarial Panel for the Evaluation of Epidemiologic Research Activities, *Report to the Secretary*, March 1990, p. i.

²*Ibid.*, p. 20.

³*Ibid.*

⁴U.S. Department of Energy, *Environmental Restoration and Waste Management Five-Year Plan, Fiscal Years 1992-1996*, DOE/S-0078P (Springfield, VA: National Technical Information Service, June 1990), pp. 57-58.

⁵*Three Mile Island Public Health Fund v. U.S. Department of Energy*, C.I.V. Action No. 1: CV-89-1185 (M.D. Pa.).

⁶U.S. Department of Energy and U.S. Department of Health and Human Services, *Draft Memorandum of Understanding for the Management of the Department of Energy Analytical Epidemiologic Research Program* (undated, 1990).

participate in State efforts to draft a dose reconstruction study at the Rocky Flats Plant. The Governor of Idaho has asked CEHIC to represent the State on a committee to review a dose reconstruction effort carried out by DOE at the Idaho National Engineering Laboratory (286).

Traditionally, CDC’s role in local public health issues has been to send small teams of scientists and physicians from the Epidemiological Investigation Service to areas reporting outbreaks of infectious disease. Such teams study the probable causes of the outbreak; design and carry out the necessary epi-

demiological investigations; and advise local officials on appropriate responses. Since its inception during World War II, the Epidemiological Investigation Service has been instrumental in the identification and control of hundreds of infectious disease outbreaks; it has also served as the training ground for a generation of epidemiologists (287).

CDC as a whole has not embraced the mission of environmental epidemiology, possibly in part because it was unclear how responsibility for environmental health issues should be divided between CDC and ATSDR. Some of CEHIC's efforts in this field have been controversial, although OTA investigations have revealed that community groups and State health agencies are pleased with and supportive of CDC efforts thus far in facilitating the Dose Reconstruction Project at Hanford.

CDC has no independent authority to investigate health problems at weapons sites and no independent source of funding for such activities. CEHIC was "invited" to lend assistance by the States of Washington and Ohio. Funding for the Hanford and Fernald projects was provided to CDC by congressional appropriations (288).

CEHIC's small staff and resources are fully engaged in current projects at the weapons sites and probably cannot take on a greatly extended role without a significant expansion in staff and funding. Also, CDC's expertise is primarily in epidemiology. It does not employ a full range of environmental scientists who could, for example, provide independent assessment of environmental monitoring data.

There is little evidence of cooperation or consultation between CEHIC and ATSDR on health issues related to the Weapons Complex. This is unfortunate because each agency has contributions to offer and the overall pool of governmental expertise in environmental health is quite limited (289).

It appears that responsibility for investigating the health consequences of weapons sites contamination will be divided so that CEHIC investigates radioactive releases and ATSDR investigates the effects of toxic chemicals. Such a division of duties will further complicate the already difficult tasks of assessing total exposure burdens and integrating the health risks resulting from exposure to multiple contaminants.

Evaluation of the State-Specific Approach to Health Assessment

State-directed health studies could presumably take advantage of all available research methodologies, including risk assessments, dose reconstruction projects, and epidemiological investigations. Colorado's plan to request proposals from independent researchers for specific studies of questions identified by preliminary monitoring data incorporates a variety of investigative tactics and could make use of the talent available in the academic and private sectors of the environmental health community. The question of how such plans might be scaled back or eliminated in the face of inadequate funding remains unanswered.

The State-specific approach to health studies also allows local community concerns to be raised and reflected in study aims and designs. Structuring such investigations so that interested members of the public can be actively involved in all steps of the research is feasible, and State health department are likely to be sensitive to such needs.

There are also disadvantages to the State-specific approach to health assessments at weapons sites. The State-specific approach, if utilized at several sites, increases the likelihood that some studies will be redundant, whereas other important health issues may go unexamined. It also lessens the chances that the investigation of generic issues—problems confronted at more than one site—will be allotted high priority, unless such issues are also of great importance at individual sites.

States will, in effect, be bidding against each other for the services of a relatively small community of environmental health professionals. In a competitive atmosphere with limited funding sources, the danger of poorly designed studies that yield ambiguous or misleading results becomes more real, especially in view of the methodological challenges that are widely recognized to plague environmental health research. Although Colorado plans to subject all submitted project proposals to peer review, some States may lack the expertise to conduct such reviews.

Also, the size of populations living in proximity to weapons sites may not provide samples for large enough statistical analysis. Adequate samples might be assembled by combining populations from communities around various sites that share common

exposures, but studies of this type would be feasible only if researchers had access to data and communities from several sites. Collaborative efforts could, in theory, be organized by individual States, but in practice this would place significant logistical demands on State officials.

Reports of an association between exposure to environmental toxicants and adverse health effects invariably engender strong and conflicting responses from different segments of a community. Affected residents are typically eager for health officials to “do something,” even when the appropriate reaction is unclear. On the other hand, indicated solutions (or even the possibility that a town has a “cancer problem”) can unfavorably affect economic development and result in angry attacks from local businesses (290). State health officials are sometimes caught in the crossfire between such warring factions of a community.

The desire to reassure worried citizens and to avoid the negative consequences of an association between toxic contamination and adverse health effects may induce some State health officials to require very stringent criteria of proof before any such association is acknowledged. The tradition in laboratory sciences is to reject any new hypothesis unless there is great confidence that it accurately portrays the true state of nature. The rationale for demanding equally strict criteria for coping with a public health incident is less clear, especially because the “natural experiments” upon which environmental epidemiology depends do not afford the level of control possible in laboratory settings (291).

The technical difficulties and time-consuming nature of environmental health studies make it very difficult to obtain incontrovertible evidence that a given exposure has caused adverse health impacts. Resource limitations sometimes force State health departments to use weak study designs and analytical techniques that almost guarantee that no definitive answers will be found, or that real associations between exposures and health outcomes will not be recognized (292-294).

CEHIC has played an important part in establishing the epidemiological study of thyroid disease that will build on the results of HEDRP. CEHIC's experience in working with DOE and individual States and its expertise in epidemiological investigations could be useful in designing future studies.

CDC also has experience in collaborating with independent scientists whose knowledge and assistance is likely to be needed in assessing possible health impacts of Weapons Complex contamination. CEHIC does not, however, possess the multidisciplinary capabilities necessary to evaluate monitoring data and to design or review exposure models.

CEHIC investigators currently involved in projects at Hanford, Fernald, and INEL appear to have the confidence of State officials and local residents. There is some danger, however, that the perception of CDC's scientific approach to health studies at the weapons sites will shift if CDC, in becoming keeper of DOE worker data (295), pursues investigations of this controversial database with anything less than aggressive vigor (see box 3-G). The condition of the MOU between DOE and CDC that permits the former to carry out initial investigations of possible community health impacts from operations and contamination at weapons sites may be especially troublesome. If CDC must await DOE permission to investigate sites or can proceed with health studies only if DOE findings indicate that a problem exists, affected communities may soon cease to regard CDC as an independent scientific body.

Summary of Site-Specific Public Health Assessments

In sum, present site-specific efforts to assess the public health implications of environmental contamination at DOE nuclear weapons sites consist of an assortment of independent, uncoordinated activities. There is no overall coordination or oversight of the health evaluations that are being planned or carried out at weapons sites, nor does any single agency currently have the authority or resources to provide such coordination and oversight.

DOE is relying on existing environmental laws and interagency agreements to provide the organizational framework for addressing possible public health impacts of weapons site pollution. This approach means that quantitative risk assessment will be the site-specific health assessment method that engages the most resources.

Quantitative risk assessments may prove useful in guiding specific remediation activities at individual sites, but the need for extensive environmental monitoring data at complex sites, and the time required to gather and review such information, may delay the availability of completed QRAs. These

delays, as well as technical and procedural problems in interpreting the policy implications of different risk estimates, may curtail their usefulness in setting near-term cleanup strategies.

Deficiencies in the scientific database that informs QRAs may limit the comprehensiveness and reliability of health risk estimates at some sites. The current process for conducting quantitative risk assessments does not encourage or, in some regions permit, the participation of affected communities. The lack of appropriate forums for citizen involvement makes it likely that some health issues of great concern to local communities will not be addressed and increases the chance that risk estimates, when finally made public, will be misinterpreted or disputed. Furthermore, risk assessments performed by DOE and its contractors may not be accepted as credible by some residents.

ATSDR will conduct preliminary health assessments at those sites that are proposed for or on the NPL, and possibly at RCRA sites as well. The need to apportion a small staff among a number of extremely complex sites, and bureaucratic delays in establishing ATSDR's presence at weapons sites, place this Agency at a disadvantage, as does its inability to enter into cooperative agreements with independent scientists. On the other hand, ATSDR's statutory mandate, its staff trained in the multiple disciplines of environmental health, and particularly, its capability for constructive engagement with communities are potentially important assets.

The abilities of individual States to design and oversee environmental health studies of the off-site impacts of Weapons Complex contamination vary, depending on the expertise of local health officials and the degree of their involvement in the cleanup. Most State health departments have few staff trained in environmental health and exercise ambiguous authority at Federal facilities. The conflicting pressures engendered by threats of adverse health impacts due to environmental toxicants may make it especially difficult for some local health officials to evaluate issues as potentially controversial as those that might result from Weapons Complex pollution.

The lack of coordination among different agencies involved in conducting health assessments at weapons sites and the competition among States for the services of limited numbers of environmental health professionals are likely to increase the costs



Photo credit: U.S. Department of Energy

K-6 Silos at Fernald containing uranium residues from the early years of Weapons Materials Production.

and perhaps diminish the quality of the resulting investigations.

Poorly designed or conducted environmental health studies can be expected to produce ambiguous or misleading results, an outcome that can only increase the distrust and anxiety of the concerned public. Erosion in the credibility of assessments of the health impacts of contamination from the Weapons Complex may contribute to the delay and costs of the cleanup if demands are raised for additional environmental monitoring, more elaborate risk assessments, or more sophisticated health studies. If the responsible health agencies do not provide credible responses to local concerns about health effects, affected communities will look to other sources, including elected officials and the courts, for satisfaction.

OTA investigations indicate that the present structure of Federal and State health assessment efforts will fail to accomplish many of the important health-related objectives integral to a successful cleanup. The next section discusses the nature and rationale for such health-based cleanup objectives.

DEVELOPING HEALTH-BASED CLEANUP OBJECTIVES

Because the scope and the complexity of Weapons Complex pollution make immediate cleanup of all contamination impossible, there is a need to identify and address in a timely manner those

sources or areas of existing contamination that pose the most significant and urgent health hazards. There is also a need to determine what cleanup levels will protect public health. The latter task may require additional research into the biological effects of toxic exposures unique to the weapons sites.

At the same time, however, the cleanup must encompass the major health issues raised by past environmental contamination and address questions that extend beyond the identification and remediation of current contamination. Failure to frame relevant health issues broadly enough may jeopardize public support for the cleanup effort as a whole.

In addition, remediation activities should include disciplined consideration of potential risks to workers and surrounding communities. Finally, methods to gauge the progress of remediation efforts should be developed.

Based on these needs, OTA has identified five basic health-related objectives that must be realized if the cleanup is to be successful. These health-related objectives are interrelated and interdependent. It is unlikely that any single objective will be realized unless significant progress is made in all five. Five health-related cleanup objectives are discussed in the material that follows:

1. addressing current and future exposure threats,
2. identifying environmental characterization and research needs,
3. satisfying community health concerns,
4. minimizing risks to cleanup workers and nearby residents, and
5. developing methods to establish remediation levels adequate to protect public health.

1. Addressing Current and Future Exposure Threats

Situations that pose a current threat of off-site exposure to toxic materials should be addressed immediately and efforts undertaken to contain all such contaminants and, where feasible, to eliminate exposure. Situations that represent a potential for future exposure should be addressed next, and so forth, until all toxic contaminants are either eliminated, securely contained and monitored, or reduced to levels consistent with the protection of public health.

To identify the most serious contamination scenarios or to craft interim strategies to prevent current

problems from getting worse, it will be necessary to assemble a reasonably complete qualitative picture of pollution at the Weapons Complex and to obtain at least preliminary data on human exposure and dose levels. Exposure estimates are key factors in evaluating the potential for, or past occurrence of, specific health impacts stemming from contamination at particular weapons sites. Obviously, health impacts cannot occur if people have no contact with toxic contaminants.

A picture of which contamination scenarios present the most significant or imminent threat of human exposure is likely to narrow the issues of urgent concern to a manageable number. Currently, there is no way of knowing which of the hundreds of areas of environmental contamination at the Weapons Complex are most pressing, or most in need of further study or interim containment action, because no complexwide strategy exists for relating environmental sampling data to possible health effects.

Until recently, only rudimentary methodologies were available for assessing individual exposure to environmental contaminants (296). More refined, multidisciplinary approaches to exposure assessment are now feasible and include sophisticated computer models that incorporate detailed environmental transport pathways, multiple human exposure routes, and demographic data of who is exposed to what. Efforts to validate such models with environmental sampling and biological monitoring (see app. D) have rendered them more reliable. In some cases, where contaminants can be detected in blood, urine, or exhaled breath, measurements of individual exposure can be obtained. These more accurate exposure models are not in wide use, however, and most biological markers of exposure remain research tools that are available for only a limited number of contaminants (297).

Exposure assessments will be included as components of the quantitative risk assessments required at all Superfund sites. Health assessments performed by ATSDR and also required by CERCLA will include assessments of how many people are potentially exposed to what toxic materials. However, these steps in the Superfund process usually do not occur until long (3 to 5 years) after environmental characterization is begun (298). Thus, many contamination scenarios within the Weapons Complex will not be subject to exposure assessments for years to come.

Whether weapons sites that are not Superfund sites will undergo formal exposure assessments *is unclear*. In addition, there is no assurance that the exposure assessments ultimately done will be of high quality. EPA, charged with the responsibility of reviewing all Superfund risk assessments, has not yet been granted the resources necessary to conduct credible oversight functions at the weapons sites.

Exposure assessments are difficult to execute and are not infallible. They will not provide a quantitative comparison of the relative risks of contamination scenarios across all weapons sites. However, as discussed, CERCLA risk estimates are not likely to establish a meaningful ranking of health risks either. Understanding where human contact with existing contamination is occurring, or is most probable, is the first step necessary to determine whether and where off-site health impacts are of concern. Robust exposure estimates are likely to be more attainable and less controversial than QRAs, and could provide, in a relatively short time, “first-cut” assessments of those areas of contamination that require immediate attention or further study. Refinements of initial exposure assessments could be carried out as additional environmental data become available.

2. Identifying Environmental Characterization and Research Needs

Situations requiring more in-depth characterization or further research should be identified early so that the requisite information is available when needed for remediation efforts.

The process of obtaining a detailed and accurate picture of the migration routes, concentrations, and chemical forms of environmental contaminants is time-consuming, *technically* demanding, and costly. It is important, therefore, that environmental characterization efforts be well planned and clearly linked to defined information needs. Preliminary qualitative exposure assessments and initial environmental monitoring data could be used to design strategies for additional environmental data collection and health studies, and they could also highlight issues suitable for further field or laboratory research.

The information needed to conduct health studies is often different from the data required to conduct a CERCLA risk assessment. Failure to think carefully about appropriate health issues or the methodology and design of proposed health studies and to

plan for the acquisition of health-specific data may delay completion of the health assessment process.

Scientists working in multidisciplinary teams would be more likely to recognize the potential health implications of early environmental monitoring results and to anticipate the additional information needed to assess possible health impacts or design remediation actions. Such a multidisciplinary approach could sharpen the focus of environmental sampling efforts and might help to contain costs or, at least, to establish whether proposed investments of time and money serve a useful purpose.

3. Satisfying Community Health Concerns

When the cleanup is complete, communities should be satisfied that good-faith efforts to achieve comprehensive analyses and effective mitigation of all significant past and present off-site health impacts have been carried out.

It is essential that the public see decisions about health impacts, cleanup strategies, and remediation goals as fair and credible. No matter how much money or effort is expended on the cleanup, many areas of great uncertainty and many controversial issues will remain. For example, situations may exist in which the best scientific analyses indicate that the safest course is to leave contaminants undisturbed, at least until improved remediation technologies are available. Some communities are likely to contest and resist such findings, however, unless the decisionmakers are perceived as unbiased and mindful of potential health and environmental impacts.

Forums for eliciting community views and ideas will be needed. The concerns that preoccupy communities neighboring weapons sites have not been addressed effectively and are unlikely to be resolved solely by compliance with environmental regulations (see figure 3-1). It is ATSDR policy to consult with local communities as part of every health assessment done at Superfund sites. However, ATSDR is unlikely to have the resources necessary to implement this policy fully. Serious and sustained efforts will be required to educate community members about technical aspects of the contamination, proposed remediation plans, and associated problems or scientific uncertainties. Similarly, DOE managers and technical experts must solicit, acknowledge, and respond to the health concerns of local communities.

Unless measures are taken to recognize and respond to the health concerns of community members, disputes over the details of regulatory compliance will likely become the focus of attention and the courts will be the arena of negotiation. Repeated challenges to the adequacy of proposed remediation strategies, along with demands for examination of and compensation for the consequences of releases from the Weapons Complex, are likely to occur. Such challenges could significantly delay the cleanup and increase costs.

4. Minimizing Risks to Cleanup Workers and Nearby Residents

Characterization and remediation activities should be conducted so as to avoid subjecting cleanup workers or off-site residents to greater health risks than those posed by the pollution itself.

The collection and analysis of some weapons site contaminants, such as the highly radioactive waste stored in tanks at Savannah River and Hanford, may impose significant risks on cleanup workers. Disturbing some buried waste or contaminated sediment may prove more dangerous to humans and more disruptive of local ecosystems than leaving the contamination in place.

Risk Assessment Guidance for Superfund does not stipulate that the risks to cleanup workers or the public as a consequence of environmental sampling or remedial actions be addressed explicitly. The need to consider possible adverse impacts of cleanup activities is obvious, however, and it would be useful to analyze these issues in a disciplined and organized way. DOE and EPA have stated that they intend to consider these factors, but no rigorous approach has yet been formulated.

5. Developing Methods To Establish Remediation Levels Adequate To Protect Public Health

Methods of measuring the threat of contamination and the progress of the cleanup should be developed and utilized to determine when remediation efforts are sufficient to protect public health.

DOE has stated that it is not clear what levels of contamination will be considered "clean enough" to satisfy regulators. Some situations, notably contamination of soil and sediments by radionuclides, have not yet been addressed by Federal law. In many

cases throughout the Weapons Complex, decisions about appropriate cleanup levels are likely to be controversial, largely because insufficient information exists to predict the health consequences of contamination. Reliable exposure data, including estimates of future exposure potential, would be helpful in such debates. If no one is exposed to, or likely to come in contact with, certain contaminants, there is at least the opportunity for careful study and discussion of alternative remediation strategies while the contaminants are securely stored and monitored.

In addition, methods of verifying the accuracy of risk estimates should be considered and applied to situations that present the highest risks or are attended by a great deal of uncertainty. There is no ready method for accomplishing this goal, but means of assaying the efficacy of remediation efforts, possibly involving ecotoxicological analyses, should be considered and developed to gauge the progress of the cleanup and to inform future remediation decisions.

CONCLUSION

Off-site health impacts are an unproven but plausible consequence of environmental contamination from the Nuclear Weapons Complex. Published reports and available data can neither demonstrate nor rule out the possibility that adverse health effects have occurred or will occur as a result of weapons site pollution. Investigations beyond those already completed will be necessary to pursue questions about the occurrence of off-site health effects and to produce the information required to identify the most pressing cleanup priorities.

DOE has barely begun to gather the data that would indicate whether off-site populations are exposed or likely to be exposed to contaminants from the Weapons Complex. DOE has not organized a coherent strategy to address the possibility of off-site exposures to toxic materials from the weapons sites or to investigate the possibility of health effects resulting from such exposures. Instead, DOE has maintained that the contamination poses no "near-term" or "immediate" health risks and is relying on the site-specific health studies called for by environmental laws and regulations to disprove the threat of long-term or chronic health impacts. This approach may prove troublesome in a number of ways.

Limitations in the scientific understanding of the adverse health impacts due to environmental toxicants make it difficult to establish conclusively the safety or degree of hazard associated with many exposures to environmental pollution. Existing chemical- and media-specific environmental standards address only a limited number of contaminants and pollution scenarios and, in some cases, were never intended to connote "safe" levels of exposure. Compliance with chemical- and media-specific standards will still leave many of the complicated situations at the weapons sites unaddressed and may fail to ensure protection of the public health in all cases.

The array of site-specific health studies stipulated by CERCLA and various IAGs is aimed at determining the nature and degree of health risks associated with environmental contamination. The CERCLA-mandated quantitative risk assessments will command much attention and resources. The data intensive nature of QRAs, the long timeframes required to collect and analyze such data, and the technical uncertainties associated with the risk assessment process make QRAs problematic as a framework around which to organize cleanup activities and will render decisions based on risk estimates vulnerable to controversy and dispute. As the QRA process is currently conducted, it does not encourage community participation or acceptance, a factor that will weigh heavily as the cleanup proceeds.

Although the creation of risk-based cleanup priorities is an attractive goal, CERCLA risk estimates may not be effective vehicles for constructing a reliable hierarchy of health risks. The failure of risk assessors throughout the Weapons Complex to use consistent inference assumptions and the great uncertainties associated with many aspects of the risk assessment process will make comparison of risk estimates very difficult.

It may prove more useful to base immediate cleanup priorities on analyses of whether and which contamination scenarios pose a potential for causing off-site exposure to toxic materials. The difficulties of determining the occurrence and extent of individual exposure to environmental toxicants are considerable, but some effective methods do exist for conducting such assessments. Given adequate resources, access to data, and appropriately multidisciplinary staff, preliminary exposure assessments at

the weapons sites could be conducted relatively quickly.

Although OTA did not evaluate site-specific environmental characterization data in detail, it is unlikely that a great many areas of contamination throughout the Weapons Complex pose a clear and significant threat of exposure to the off-site public. Comprehensive and scientifically rigorous exposure assessments would probably reveal that only a small number of the thousands of areas of contamination present the risks of human exposure. Such assessments could thus provide a scientifically credible foundation for identifying health-based characterization and cleanup priorities.

The scientific challenges involved in linking particular exposures to specific health outcomes are formidable. The information available to OTA indicates that the most probable off-site exposures will involve exposure to low doses of contaminants occurring episodically or over long periods. Scientific understanding of what, if any, biological effects result from such exposure patterns is very limited. Therefore, it is important that health studies investigating such linkages be carefully designed and take advantage of all available research techniques and scientific talent. Poorly designed studies are likely to yield ambiguous or misleading results and to further alienate an already skeptical public.

The ATSDR health assessment effort is problematic because it does not appear to be supported by sufficient resources to ensure that completed assessments are comprehensive and scientifically sound. In some instances, health studies negotiated in interagency agreements, or initiated at the request of individual States, may accomplish some public health objectives at individual sites, but the quality and scope of such studies are likely to vary across the Weapons Complex. It remains unclear whether State-sponsored health studies agreed to in IAGs will proceed if DOE fails to obtain appropriations adequate to its commitments.

The fundamental problem involved in assessing the off-site health effects due to pollution at the Nation's nuclear weapons sites is not, however, simply a matter of uncertainties or gaps in the science but has much to do with the coherence and credibility of the process employed to carry out such assessments. The responsibility for conducting off-site health evaluations is currently dispersed among several Federal and State agencies, none of which

has sufficient staff or resources to effectively design, coordinate, or oversee the conglomeration of site-specific health studies called for by law or inter-agency agreements. The available talent in environmental health sciences is limited; government agencies must have access to the expertise available throughout government and in the academic and private sectors if state-of-the-art research methods are to be employed. If professional and other resources are not efficiently utilized and coordinated, State and Federal agencies will be competing against each other for funding and expert advice. This situation is likely to affect the caliber of health studies performed throughout the Weapons Complex, increase the likelihood that some studies will be of poor quality and, by inciting controversy and demands for repeated studies, increase the overall costs of the cleanup.

The current processes and procedures for conducting site-specific health studies lack adequate forums for allowing members of affected communities and the interested public to voice their concerns. The fear and anger that now beset some communities surrounding weapons sites must be replaced by a realistic appreciation of what is known and what is uncertain about past or current health risks from decades of nuclear weapons production. The public must understand the appreciable difficulties involved in studying the potential health effects associated with particular waste sites. Definitive answers to some important questions may simply not be attainable with existing research methods. A process is needed that would assist affected communities or their representatives in understanding the technical details and uncertainties of environmental characterization and health assessments; and that would permit the affected public to participate in weighing the tradeoffs implicit in making cleanup decisions and in setting priorities.

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