

NIOSH Responses to Comments Received on the Draft Report Entitled
“An Assessment of the Feasibility of a Study of Cancer among Former Employees of the
IBM Facility in Endicott, New York”

May 27, 2008

Introduction

In March 2007, the National Institute for Occupational Safety and Health (NIOSH) released a draft report on the feasibility of a study of cancer among former employees of the International Business Machines (IBM) facility in Endicott, New York and invited public comment. NIOSH received public comments from organizations, from scientists, and from other private citizens. These comments are posted on the NIOSH website at <http://www.cdc.gov/niosh/docket/NIOSHdocket0103.html>.

NIOSH is currently preparing a draft study protocol should the necessary funds to conduct the study be appropriated. Funds for the study were not included in the FY08 appropriations. Further work beyond protocol development will depend on availability of sufficient fiscal support in FY09.

The purpose of this document is to respond to questions or comments related to the feasibility or conduct of such a study. Comments not directly related to the conduct of a study are not included. For example, a number of comments described the working conditions at IBM, provided information on former workers who developed cancer, or concerned environmental exposures in the Endicott area. Community concerns about environmental issues are being addressed by ongoing efforts by the Agency for Toxic Substance and Disease Registry (ATSDR) and the New York State Department of Health (NYSDOH). More information about these efforts can be found at the following website: <http://www.health.state.ny.us/environmental/investigations/broome/>

This document lists comments received from organizations, individual scientists, and private citizens as well as responses to those comments. Many of the comments expressed support for a study of cancer among individuals who worked for IBM in Endicott, NY. These comments, as well as the single comment opposing a study, are summarized separately at the end of the document. The responses assume that NIOSH researchers would direct a study of cancer among workers formerly employed by IBM at Endicott if funding becomes available.

Major recurring comment themes included the following:

1. Concern about who would be included in the study (workers at facilities beyond Endicott, contract workers, summer and temporary hires);
2. Sources of information for determining which workers were exposed, as well as who became ill;
3. Recommendations to include former workers and perhaps citizens in design and information gathering for the study;
4. Concern about what types of health outcomes would be included (non-cancer outcomes, birth defects);
5. Concern about who would serve as a comparison group for evaluating the health of Endicott workers (general population, healthy workers, local populations?);
6. Concern about the power of the study to detect any increased risks for adverse health effects;

7. Concern about the organizational unit for evaluating exposures (classifying exposures using department or building);
8. Suggestions that follow-up nested case-control studies be considered.

In addition, a number of comments assumed that the purpose of the study would be to evaluate the effects of exposure to trichloroethylene (TCE). We wish to emphasize at this time that TCE is only one of a number of chemicals used at the facility. The intent of this study would be to evaluate the health outcomes of Endicott workers, compare these to outcomes expected based on non-worker populations, and to examine through comparisons among Endicott workers whether any adverse health outcomes appear to be related to workplace exposures. Given the large number of chemicals used at the facility and the large number of processes conducted over time, the effects of individual chemical exposures may be difficult to identify. In addition, records which can be used to identify which workers were likely exposed to specific chemicals, and at what level, are limited. The historical work process and availability of information may necessitate grouping of similar chemicals. If an increase in a specific type of cancer is observed among groups of workers using certain groups of chemicals, a follow-up nested case control study may provide additional information on the role of specific chemicals.

A. COMMENTS FROM SCIENTISTS AND/OR ORGANIZATIONS

Richard Clapp, D. Sc., M.P.H., Boston University School of Public Health

Comment:

It will be important to compare the cancer mortality experience to a reference group of workers and not just the “general population” as described on p. i-ii of the Executive Summary. The NIOSH reference group of workers would be a way to do this, if it is available for the relevant time period. There are several other options that should also be considered, such as standardized mortality odds ratio (SMOR) or proportionate cancer mortality ratio (PCMR) for mortality analyses.

Response:

We agree with the importance of comparing the cancer mortality experience to a reference group of workers. No suitable comparison rate file for workers currently exists. However, if the study goes forward, we feel the most accurate assessment can be made by performing internal analyses comparing Endicott workers who were likely unexposed or minimally exposed to those with longer or greater exposures.

Comment:

The ECHOES (Environmental, Chemical, & Occupational Evaluation System) database was started earlier than 1987, so it is unclear why it could only be useful for the years 1987-1992.

Response:

Our understanding is that ECHOES was implemented at the Endicott site starting in 1987 and that CHEMS (Chemical Health and Safety Environmental Management System) started earlier and served as the source of industrial hygiene sampling data in ECHOES. However, if a study is conducted, we would further evaluate both databases.

Comment:

The cancers of interest, and for which power calculations were done, are limited. There is good evidence that non-Hodgkin lymphoma is associated with several chemicals to which Endicott workers were exposed. Furthermore, brain and central nervous system cancer have been shown to be elevated in maintenance and repair workers in the IBM Burlington plant (Beall, et al., 2005) and in IBM manufacturing workers (Clapp, 2006). It would be worth including power calculations for these, as well.

Response:

The cancers for which power calculations were conducted do not necessarily reflect the cancers of *a priori* interest. Power calculations were conducted for several cancers including a relatively rare cancer (i.e., testicular cancer) and a relatively common cancer (i.e., lung cancer) to provide information on the power of the study to detect a significant increase in a variety of cancers. If a study is conducted, a study protocol will be prepared. Cancers of *a priori* interest would be identified in this protocol.

Comment:

The input of former IBM Endicott employees is vital to the success of the cohort study. A formal mechanism for including them in the study as advisors should be developed; the feasibility study has already benefited from their involvement as have other studies of IBM workers.

Response:

We agree that it is important to obtain input from former IBM Endicott employees, particularly for the exposure assessment component of the study. If a study of cancer is conducted, a process for obtaining such input from former IBM Endicott employees will be developed and included in the study protocol.

Comment:

The protocol for the cohort study should include a specific decision process for going further with a nested case-control study.

Response:

The decision to consider pursuing any nested case-control studies would be based on findings of the cohort study, the potential for a case-control study to answer specific scientific questions about the cohort study results, and the availability of funding. These factors would be addressed in the protocol for the cohort study.

Marilyn Campbell, Ph.D.

Comment:

In the power calculations, person-years has been used as the unit of analysis. There are problems with this approach. It generally assumes a constant hazards model. This was the model used in the Nurse's Health Study that led to the erroneous recommendation of hormone replacement therapy (HRT) for menopausal women. See the 2005 Oxford publication by Kraemer, Lowe, and Kupfer *To Your Health*, p. 90. Do you plan to analyze the Endicott data this way? Hopefully not.

Response:

The article referenced highlights the need to consider age-related changes in risk. If a cohort study is conducted, we would initially conduct life table analyses. These analyses use person years as the unit of analysis but stratify on age, sex, and race in statistical calculations. The age stratification addresses the problem of increasing hazards with older age mentioned in the article. We also would conduct additional analyses to evaluate whether workers who probably had contact with chemicals at work, or who worked in certain departments, were more or less likely to develop or die from cancer than other workers. These analyses would examine temporal factors such as time since exposure and cohort effects.

The power calculations we performed considered age-related changes in risk.

Comment:

Are you interested in cancer occurring during the work years only or occurring during any point in time from 1965 to 2004, even into retirement?

Response:

Once a worker meets study eligibility criteria (e.g. a minimum time employed at the facility), any cancer occurring during the study period, regardless of whether the worker is actively employed or retired, would be included.

Comment:

Will different samples be selected from the defined database at different point in time— i.e., a true cohort study, and the cancer diagnoses noted, or will there be a panel design in which the same employees are followed over the study duration and cancer diagnoses are noted.

Response:

The study would involve a dynamic cohort, with participants entering the cohort as they meet the cohort membership criteria.

Comment:

What time intervals will be used for determining the number of cancer diagnoses or cancer rates? Yearly? Five-year intervals?

Response:

The life-table portion of the study employs stratification on 5-year age and calendar time periods (with different periods used in the lowest and highest strata).

Comment:

Why not use building as a first pass at the analyses, then look at departments within buildings.

Response:

Based on information from the feasibility study, department may be the most appropriate surrogate for chemical exposure. If a study of cancer is conducted, we would further evaluate the use of division and job title data to refine the department-based exposures evaluations. Building data were not identified as a useful primary method of categorizing workers in the feasibility study. Notes from visits to IBM indicate that building information may be available for some industrial hygiene data, but corresponding building data were not available in the electronic personnel or work history data for individual workers. However, building data may be useful in some cases to evaluate the likelihood of indirect exposures due to physical proximity of different departments.

Comment:

IBM pumped wastewater for many years into the Susquehanna River. This may have greater significance for the entire surrounding Endicott area.

Response:

Environmental concerns outside the facility are beyond the scope of a NIOSH occupational epidemiology study. We suggest addressing questions about environmental concerns to the New York State Department of Health or the Agency for Toxic Substances Disease Registry (ATSDR), as both organizations have considered questions of exposures outside the facility.

Comment:

IBM employee health records should be obtainable from Blue Cross/Blue Shield and from retirees' Medicare and United Health service records.

Response:

If a study is conducted, we would explore the utility of these and other available records. However, it is likely that these sources would not be used because NIOSH plans to use a number of vital statistics information providers, as well as cancer registries, to obtain cancer incidence and death data. Those sources are more comprehensive, particularly because many former employees who developed cancer probably had other health insurance coverage at the time of diagnosis and treatment. Cancer death data and cancer registry data are likely to be more complete for the geographic regions they cover, especially in later years. It is estimated that the New York State Cancer Registry, which began in 1976, currently captures 95% or more of cancers (excluding basal cell skin cancers) diagnosed among residents of New York State excluding New York City.

Comment:

Include all cancer diagnoses and then sort on the cancers of interest. It is interesting to note that you have not included breast cancer and ovarian cancer. The rationale for this is unclear as these cancers occur at a greater rate than does testicular cancer.

Response:

As discussed above, we conducted power calculations for several cancers including a relatively rare cancer (i.e., testicular cancer) and a relatively common cancer (i.e., lung cancer) to provide information on the power of the study to detect a significant increase in a variety of cancers. If a study is conducted, all major cancers, as well as major categories of non-cancer outcomes, would be evaluated.

Comment:

Some work history records were lost when a data file went missing. Will the loss of this database interfere in any way with your study?

Response:

We obtained electronic personnel and work history data from IBM before computer tapes containing personal data for some former IBM employees were reported lost by the Poughkeepsie Journal (April 24, 2007). As a result, we do not anticipate that the loss of these data would interfere with a study.

Comment:

Many of the “probable” chemicals listed in your feasibility study are associated with central nervous system (CNS) effects, particularly with long-term exposure, according to the Environmental Protection Agency (EPA) and Centers for Disease Control and Prevention (CDC) websites. Why not capture possible CNS diagnoses codes in the data and save for a future study?

Response:

If a study is done, mortality from both cancer and non-cancer outcomes would be determined by linking workers to national death data. Thus, deaths from central nervous system disorders would be captured. However, diagnoses of central nervous system disorders that are not fatal would not be captured because, except for non-malignant brain tumors, there is no national or New York State registry of these conditions.

Comment:

Will your sampling capture a work history of someone employed first in the 1950s and last in the late 1980s who worked in production (summary, actual comment more specific and lengthier)?

Response:

If a study is conducted, a protocol would be prepared that describes the cohort criteria (i.e., who would be included in the study). Rather than sampling, the study would include all IBM employees who meet the study eligibility criteria. We would include all workers who were employed for more than one year after the beginning year of the study. Some of the considerations in selecting the year in which to begin the study are described in Table A on page 22 of the final draft feasibility report. A person who was first employed in the 1950s and last employed in the late 1980s in production would almost certainly be included in the study.

R. Garruto, Ph.D., State University of New York (SUNY), Binghamton

Comment:

Follow-up interviews with former IBM employees who developed cancer (or with their spouses or first degree relatives) back to 1965 should take place to obtain missing data or to clarify inconsistent data from the IBM database records.

Response:

If a study is conducted, we would be able to resolve some of the data gaps and discrepancies using national databases. We may also be able to resolve some of the data gaps and discrepancies using additional records from IBM (e.g., hard copy personnel records or medical records). Conducting interviews with former employees to resolve data discrepancies would not be a systematic approach unless we could contact every former employee, and this is beyond the scope of the cohort study. NIOSH investigators would attempt to resolve data discrepancies for all study subjects, regardless of health outcome.

Comment:

It would seem imperative to interview former IBM employees regarding issues of exposure, the chemicals used, and the departments and categories of employees impacted.

Response:

We agree. If a cohort study is done, we would seek information from a group of former IBM employees in the exposure assessment phase of the study.

Comment:

A follow-up nested case-control study comparing former IBM workers with cancer to a group of workers without cancer should definitely be done as recommended by NIOSH in their feasibility assessment. This will also help clear up issues regarding medical histories, lifestyle choices including smoking, and prior employment questions at IBM and elsewhere.

Response:

As indicated above, the decision to consider pursuing any nested case-control studies would be based on findings of the cohort study. Worth noting is that while case-control studies are better able to control for some of the factors raised in the comment, some uncertainty remains even with this study design.

Comment:

If it is found that an increased risk of cancers in IBM workers appears to be workplace exposure related, then studies in the community neighborhoods should be initiated. Since environmental exposures to toxic chemicals from IBM activities and spills have been reported, it is important to determine if there is an excess of birth defects as well as childhood and adult cancers in impacted neighborhoods.

Response:

NIOSH is responsible for conducting research and making recommendations for the prevention of work-related injury and illness.

The New York State Department of Health (NYS DOH) and Agency for Toxic Substances and Disease Registry (ATSDR) conducted a health statistics review of cancer and adverse birth outcome incidence among residents of the Endicott area, released as a health consultation in May 2006, and a follow-up health statistics review, released for public comment in March 2007. These reports can be accessed through the NYS DOH website: <http://www.health.state.ny.us/> or, for the May 2006 Health Statistics Review http://www.health.state.ny.us/environmental/investigations/broome/hsr_health_consultation.htm; for the March 2007 Follow-up Health Statistics Review Public Comment draft http://www.health.state.ny.us/environmental/investigations/broome/hsr_public_comment_draft.htm.

William B. Grant, PhD.
Sunlight, Nutrition, and Health Research Center

Comment:

Compare cancer rates for former employees of IBM-Endicott with controls living in the same place as the subjects to control for factors such as solar ultraviolet-B radiation and vitamin D production, while taking care to account for those who moved to sunnier locations.

Response:

If a cohort study is conducted, we would perform internal analyses to control, as far as possible, for environmental factors that cannot be directly addressed by the study. In these analyses, unexposed (and possibly minimally exposed) IBM Endicott workers would be used as the comparison population

Comment:

Suggest using lung cancer incidence or mortality rates to assess the effects of smoking on cancer risk.

Response:

We agree that examining incidence or mortality rates for smoking-related diseases or causes of death can be helpful in assessing the role of smoking in health outcomes in the cohort. We generally examine not only lung cancer, but also other smoking-related cancers (as identified by IARC, the International Agency for Research on Cancer), and also emphysema and chronic bronchitis.

Western Broome Environmental Stakeholders Coalition (WBESC)

Comment:

The exposure should be associated with a department or workers performing similar tasks.

Response:

The feasibility report indicates that potential for exposure to chemicals can probably be associated with the departments in which employees worked. Data regarding workers performing similar tasks would be valuable but has not been identified as available.

Comment:

The study should compare the IBM workers to healthy workers and not the general population.

Response:

We agree with the importance of comparing health outcomes in exposed workers to those in a reference group of workers, as well as the general population. If the study goes

forward, we would perform internal analyses using unexposed and minimally exposed IBM Endicott workers as the comparison population.

Comment:

If IBM does not provide workers' records, NIOSH should subpoena the records.

Response:

If a study is conducted, NIOSH will make every effort to obtain the records necessary for the conduct of the study.

Comment:

The main concern of the study should be TCE; the other chemicals should also be studied.

Response:

According to the Health Statistics Review Protocol published by NYSDOH in 2004, TCE is an environmental contaminant of concern in the Endicott area. The protocol notes that IBM-Endicott has been identified as one source of the groundwater and soil gas contamination. However, employees at the IBM facility worked with many other chemicals as well. TCE was not necessarily the major workplace hazard for all Endicott employees. While the cohort study would ideally address the effects of exposures to some specific chemicals such as TCE, the feasibility report found that some subsets of workers were exposed to numerous chemicals, and the effects of individual chemical exposures may be difficult to identify. In addition, records which can be used to identify which workers were likely exposed to specific chemicals, and at what level, are limited. The historical work process and availability of information may necessitate grouping of similar chemicals. If an increase in a specific type of cancer is observed among groups of workers using certain groups of chemicals, a follow-up nested case control study may provide additional information on the role of specific chemicals.

Comment:

The main concern is cancer; non cancer disease should also be studied. Included should be birth defects of children of workers.

Response:

Non-cancer mortality would certainly be examined in the study. The incidence of non-cancer diseases may be examined at a later point if significant elevations are found in deaths from diseases for which registries exists, such as non-malignant brain tumors.

Assessment of birth defects in children of workers would depend on availability of additional resources, beyond those needed for a study of cancer. In addition, such a study would be limited to workers residing in New York State after 1982, when the New York State Congenital Malformations Registry became operational statewide (with the exception of New York City). Although the Endicott site is located close to the Pennsylvania border, birth defects among children of workers living in Pennsylvania cannot be evaluated, as Pennsylvania does not have a birth defects registry. According to

information in the electronic files NIOSH obtained from IBM for the feasibility study, 86% of employees resided in New York, 6% in Pennsylvania, and 2% in Florida (note that the last two figures were inadvertently reversed in the feasibility report). Matching to the birth defects registry would involve additional costs. Moreover, information on important factors such as maternal tobacco and alcohol use during pregnancy may need to be obtained from birth certificates, further adding to study costs. Finally, adding a birth defects component would necessitate an increase in funding to cover project staff time for data collection, coding, and analysis.

Comment:

NIOSH should summarize the comments and respond to the comments in a forum such as a WBESC meeting.

Response:

Responses to the comments will be posted on the following website:

<http://www.cdc.gov/niosh/docket/NIOSHdocket0103.html>.

We anticipate meeting with WBESC and other stakeholders to discuss our responses and next steps.

Comment:

The study should address such questions as the following: what was the worker exposure? Skin, inhalation?

Response:

Information from the feasibility study did not address routes of exposure. For certain tasks during certain periods of time, especially the early days of plant operation, the routes of exposure may be difficult to determine. If a study is conducted and such information is available in the detailed industrial hygiene records, we would plan to evaluate this information to determine whether it would be useful in categorizing exposure groups.

Comment:

Prepare a task list and a timeline for the study. NIOSH should prepare a progress report to WBESC on a quarterly basis when the study begins.

Response:

If a study is conducted, a timeline will be developed. We would plan to update WBESC and other stakeholders on an annual or semi-annual basis and also provide interim updates as major steps in the study are completed.

Comment:

The records that will be used are as follows: national death records, state cancer registry, working history and chemicals used, ECHOES database and the Corporate Mortality File.

Response:

If a study is conducted, we would explore the utility of these and other available records. It is likely that the corporate mortality file would not be used because NIOSH uses vital status information from national sources such as the National Death Index and the Social Security Administration. Those sources are more comprehensive and, in particular, more likely to accurately ascertain the vital status of former workers who have moved away from the local area.

Larry Cohen, President, Communication Workers of America (CWA)

Comment:

The proposed NIOSH cancer study would add significantly to an understanding of multiple chemical exposures and the development of chronic diseases. Different groups of workers were exposed to different types and/or amounts and/or combinations of these chemicals. Therefore, assessing cancer rates by department may make it possible to look at the relative risk of specific chemicals or chemical combinations to the development of cancer.

Response:

A study would evaluate the utility of departments in assessing exposures and may use department to examine health outcomes as well.

Comment:

Another important feature of the NIOSH study would be the ability to characterize and evaluate the chemical exposures and related worker health outcomes at the Endicott, New York, facility and, in turn, generalize these findings to other U.S. electronics facilities and affected workers. As identified in a CWA review of relevant scientific studies specific to working conditions within the U.S. electronics industry, many of the same chemical products are used and many of the same work processes are conducted by affected workers. Thus, regardless of the employer and work location, one might anticipate identifying similar working conditions and health problems among comparable workers involved in similar work processes. Action taken to generalize the findings from the NIOSH study in Endicott would prove to be a significant achievement in terms of the health and well-being of all affected workers.

Response:

The generalizability of a study to workers in other facilities across the U.S. electronics industry would be limited for several reasons.

Some products manufactured at the IBM-Endicott facility were unrelated to the electronics industry (eg. guns). In addition, IBM did not make computer chips in

Endicott, so a study of the facility would not provide information about this or other aspects of the industry outside the scope of this facility's product line. Findings of the study would be most applicable to other facilities engaged in production activities, such as packaging, which were carried out at Endicott.

Furthermore, chemicals and processes that were used in production at Endicott changed over time. If a study is conducted, we will attempt to obtain information on major changes over time in the exposure assessment component of the study.

Elizabeth O'Brien
Manager, Global Lead Advice and Support Service

Comment:

I trust the study will look into exposure to lead fumes for the circuit board workers, as lead is now regarded as a probable human carcinogen and IBM should have blood lead records going back further than any other biological monitoring for an occupational exposure?

Response:

If a study is conducted, we would explore the availability of biological monitoring data for lead and other substances and the possibility of evaluating the health effects of exposure to specific chemicals. It is likely to be cost prohibitive to evaluate such monitoring data in a cohort study, but this approach may be feasible for a follow-up nested case-control study pertinent to this exposure.

Amanda Evans, President and Founder, and Tom Griffith, Ph.D., Director, Victims of TCE Exposure (VOTE)... A Lasting Legacy

Comment:

If the suggestion of an IBM nested case control study does go forward, we at VOTE would like to see the development of the dose-response data and are hoping that NIOSH is somehow able to identify and inform those IBM workers that have been most exposed to TCE so they can seek preventative medical care for possible health risks.

Response:

In accordance with NIOSH practice, once a study is completed, we would notify all members of the study cohort of the findings. Recommendations would be made, based on study results. However, as noted above, the feasibility report found that some workers were exposed to numerous chemicals so the effects of individual chemical exposures may be difficult to identify. In addition, records which can be used to identify which workers were likely exposed to specific chemicals, and at what level, are limited. As a result, it may not be possible to separate out workers exposed to TCE or to develop quantitative or semi-quantitative dose estimates for TCE to identify the workers who were most exposed.

Comment:

We would like to see NIOSH and the New York Department of Health inform and include the IBM workers in three useful things...:

1. The IBM workers should be given a list of local and or physicians within New York State who have completed the ATSDR's TCE Physician's Education Program.
2. Local physicians should be notified via NIOSH or IBM workers of the opportunity to participate in the TCE Physician's Education program.
3. It would be very beneficial to have the IBM workers included in the New York State volatile organic compound (VOC) Exposure Registry.

Response:

As noted above, while the NYSDOH Health Statistics Protocol Summary notes that TCE is an environmental contaminant of concern in Endicott, workers at the IBM facility worked with many other chemicals as well, and TCE may not have been the major workplace hazard for all exposed employees. While the cohort study would ideally address the effects to exposures to specific chemicals such as TCE, this may not be possible (please see introductory comments related to this issue).

After the study is completed, we would notify workers of study findings and make any recommendations for appropriate prevention or follow-up measures.

Study findings would be conveyed to ATSDR and NYSDOH. Actions such as those recommended by the reviewer would be considered by those agencies.

Comment:

We believe that participation of affected citizens and/or workers in the study design, protocol, and dissemination of study findings is crucial to the success of a scientifically valid TCE study. VOTE encourages the creation of a Citizen Advisory Group for this purpose. We also encourage a study design that is free from industry bias as this may jeopardize the validity of the study.

Response:

NIOSH conducts studies independently and makes every effort to base its findings on rigorous, objective scientific methodology. NIOSH obtains reviews of study protocols, and of manuscripts describing public findings, from expert peer reviewers as well as from diverse primary stakeholders such as site management, workers, and state and federal government. As stated above, it is important to obtain input from former IBM Endicott employees, particularly for the exposure assessment component of the study. If a study of cancer is conducted, a process for obtaining such input from former IBM Endicott employees would be developed and included in the study protocol.

We would like to reiterate that the purpose of a cohort study would be to generally evaluate the effects of workplace exposures at IBM Endicott on specific health outcomes,

and that the ability to identify workers exposed to and evaluate the effects of TCE specifically may be limited.

Donna Lupardo, Assembly Member, State of New York

Comment:

It is critical that contracted workers be included in the study. Local unions (Service Employees International Union (SEIU) Local 200 United and Plumbers and Pipefitters Local 112) had members contracted to work at IBM Endicott during the study timeframe, and information about these individuals is available. All the former workers at IBM deserve to know if they have been exposed to health risks

Response:

We appreciate the information about pertinent labor unions representing contract workers at Endicott. If a study is conducted we would evaluate the feasibility of identifying contractors and reviewing their records.

B. PRIVATE CITIZEN COMMENTS:

Comments from a former regulatory official writing as private citizen:

Comment:

Warns against classifying exposures by departments. Also cautions against assuming that exposures to non-critical wet-process personnel were de minimis without evidence of this. The transit through non-process employee areas of mobile carts holding components "in process" was substantial. Exposure to VOCs was much more widespread through the employee population than suggested by job descriptions. Do not assume that exposures to non-critical wet-process personnel were de minimus. Collect information on the size of equipment and the dimensions of its evaporative interface to ambient workplace error.

Response:

If a study is conducted, we would consider other work units such as building, where possible, to help determine these "nearby" or "in transit" exposures.

Comment:

Need to interview a large sample of the cohort through the entire time period to be studied to determine exposures. Need to deal with dermal exposure as well. Employee interviews can provide information on safety precautions, if any, that were used. Suggests use of the internet to find retired and current workers.

Response:

If a study is conducted, we would contact both active and retired employees to learn more about work processes and organization.

Comment:

It would not be surprising if the feasibility report is not totally correct in estimating the lack of scientific feasibility in development of quantitative estimates of exposure for former employees.

Response:

Based on the data that were reviewed for the feasibility report, it does not appear feasible to develop quantitative estimates of exposure. However, if a study is done, we would evaluate the available data in more detail.

Individual Private Citizen Comments:

Note: In cases where several private citizens expressed similar concerns, the comments have been grouped together.

Comment:

Concern that results will be diluted by having administrative and non-line engineers in the study. Concern that IBM-sponsored study was flawed by including workers not exposed to chemicals. Only include workers who had some exposure to chemicals.

Response:

It is useful to include workers with little, if any, exposure to chemicals so they can serve as a baseline for comparison to workers with greater exposure to chemicals.

Comment:

Concern about loss of records by IBM.

Response:

As noted above, we obtained the electronic personnel and work history data from IBM before computer tapes containing personnel data for some former IBM employees were lost. As a result, we do not anticipate that the loss of these data would interfere with a study.

Comment:

Concern about spills, leaks, emissions, and amount of chemicals recovered; suggestion to get this information.

Response:

If a study is conducted, we would evaluate the feasibility of obtaining this information and using it in the exposure assessment component of the study.

Comment:

Concern about inability to distinguish between occupational exposures and lifestyle and environmental exposures.

Response:

The inability to completely control for non-occupational exposures is certainly a limitation of occupational epidemiology. However, we would evaluate the likelihood that such exposures are responsible for any observed health effects. For example, the likelihood of confounding by smoking can be assessed to some extent by looking at whether mortality from smoking-related illnesses exceeds that found in the general population. A follow-up case control study could also be considered if questions remain about the role of lifestyle and environmental exposures in the cohort study results.

Comments:

Concern about including “vendors” in the study because most worked in same jobs, in the same areas, for the same length of time.

College summer workers used beakers of TCE to clean circuit boards. They worked under lab hoods & used gloves, but fumes remained.

Comments that in the mid 1980s, work was farmed out to vendors like ADC, Hadco, and Chenango Industries.

Concern that IBM safety/industrial hygiene (IH) did not sample spills, leaving it to the contractors.

Concern about excluding temporary workers employed at least than one year. The temporary workers had the most contact with chemicals.

Comment that it is best to focus on a basic IBM cancer study. If that shows there is a problem then possibly contractors and temporary workers can be looked at later.

Response:

We would evaluate the feasibility and cost of adding contract, temporary, and summer college workers. The feasibility of including temporary workers employed less than one year is doubtful unless the study is limited to employees who worked in 1984 or later. Employees who worked for less than one year before 1984 are not included in the company electronic personnel records.

Comments:

Concern that workers (current and retirees) be notified that the study is going to occur.

Request to be put on a mailing list. Requests for study results.

Response:

If NIOSH receives funding and initiates a study, we would develop a mechanism for informing and updating stakeholders.

Comments:

Concern about who would be included in the study, and how to be included in the study

Worker suggests advertising for IBM employees to contact NIOSH if they or a family member worked in a chemical area.

Response:

Examining company work history records has been determined to be the most effective method to identify IBM employees who worked in areas where chemicals were used. However, if a study is done, we would also seek input from current and former IBM employees on work processes and organization.

Comment:

Concern that only residents of Endicott and those who worked in certain buildings would be included in this study.

Response:

If the study is conducted, the study would include people who worked for IBM at all locations or buildings associated with manufacturing in Endicott, New York. The study would not include residents of Endicott who did not work for IBM.

Comment:

I would like to be added to the inquiry – request to have my health/work record included in the feasibility study. Who do you report cancer information to? Can I be in the study?

Response:

Individuals do not have to submit any information to NIOSH to be included in a study. If a cohort study is done, workers would be identified from company records and cancers would be identified from national death data and cancer registries. If, however, a follow-up case control study is done, some workers or their families may be contacted and asked to complete a questionnaire or telephone interview.

Comment:

I urge you to include follow-up with all former IBM employees. The study should include a nationwide survey of people who worked at the IBM Endicott site.

Response:

We believe that the approach recommended in the draft feasibility report would be a better approach than a nationwide study. It would be very difficult and costly to locate, contact, and administer a survey to all former employees who were eligible for the study. It is likely that many of those workers would not be located.

Comments:

Request for study of East Fishkill.

Include the Oswego plant.

Why aren't the Poughkeepsie employees included? Heated TCE was used in the production process.

Include IBM Customer Engineers from across the country who in the 1940s, 1950s, and 1960s, frequently worked with their hands submerged in "IBM Cleaning Fluid," which was one form of TCE.

Do you plan on doing a study of the people who worked on the Cottle Road plant in San Jose?

Response:

We assessed the feasibility of, and generated cost estimates for, a cohort study of workers at IBM-Endicott. Any expansion of the study would necessitate additional resources and would greatly extend the study timeline.

Comment:

Suggest getting incident reports from the nurses' station.

Response:

If a study is conducted, we would evaluate both medical and industrial hygiene data sources. However, the task of systematically examining all hard-copy incident reports may not be feasible for an initial large cohort study.

Comments:

Comments about specific tasks, areas, and hazards.

Focus study on machine assembly area, mostly building 46.

Focus on specific buildings, including building 18.

Response:

If a study is conducted, we would include workers who worked in all the IBM buildings and/or locations in Endicott that were associated with manufacturing. As we noted previously, it may not be possible to identify which employees worked in which buildings. Thus, we may not be able to focus on specific buildings. However, it does appear feasible to focus on specific departments.

Comment:

Include polychlorinated biphenyls (PCB) in the study, because capacitors used had PCB in them and exploded regularly

Response:

If a study is conducted, we would consider the health effects of exposure to specific chemicals such as PCBs. However, as noted above, some workers were exposed to numerous chemicals, and the effects of individual chemical exposures may be difficult to identify. In addition, records which can be used to identify which workers were likely exposed to specific chemicals are limited.

Comments:

Concern about health outcomes:

Why is the focus on cancer only? What about lung disease? Will depression be included?

Response:

As indicated in response to a previous comment, if a cohort study is conducted, fatal non-cancer outcomes would be determined by linking workers to national death data. Thus, deaths from lung diseases would be captured. However, cases of lung disease and depression that did not lead to death would not be captured because there is no national or New York State registry of those conditions.

Comment:

Is there any plan to expand the study beyond just cancer rates for people exposed to the plume?

Response:

If NIOSH conducts a study, it would be a study of cancer among people who worked for IBM in Endicott and would not be defined by exposure to the plume. The study would also evaluate worker deaths from non-cancer outcomes.

The New York State Department of Health (NYS DOH) and Agency for Toxic Substances and Disease Registry (ATSDR) conducted a health statistics review of cancer and adverse birth outcome incidence among residents of the Endicott area, released as a health consultation in May 2006, and a follow-up health statistics review, released for public comment in March 2007. These reports can be accessed through the NYS DOH website: <http://www.health.state.ny.us/> or, for the May 2006 Health Statistics Review http://www.health.state.ny.us/environmental/investigations/broome/hsr_health_consultation.htm; for the March 2007 Follow-up Health Statistics Review Public Comment draft http://www.health.state.ny.us/environmental/investigations/broome/hsr_public_comment_draft.htm.

Comment:

The IBM employees deserve a proper health assessment.

Response:

If a study is done, the study would evaluate whether employees are more likely to develop or die of certain cancers than the general population and whether employees who

had potential exposure to chemicals or worked in certain departments were more likely to develop or die from certain cancers than other workers. The study would not involve health assessments of former or current IBM employees.

Comments:

Concerns about health outcomes

Concern about identification of all cancers

Suggests that hospitals in the area turn over their records to ensure accuracy in cancer diagnoses.

Suggests allowing individual IBM employees to submit their individual cancer experiences by name or employee number. Suggests asking for input from workers on the names of IBM workers they know that had or have cancer and the type. Concern that some employee cancers were not reported within the company during certain periods of time.

There should be a more extensive review done other than the records that IBM has to make sure you are getting the full story. I believe the study needs to dig deeper and that there should be some interviews with former employees or their families.

I understand your comments on the cancer registry but is that complete and will it provide the data that is needed to ensure that you can provide a full assessment?

Response:

Identifying cancers by linking former employees with mortality and cancer registry data was determined to be the best approach because it would avoid introducing bias into the study and would be more efficient. Cancer death data and cancer registry data are generally quite complete. Cancer registry data is available from 1976 for New York, 1985 for Pennsylvania, and 1981 for Florida, the states of residence for most former employees probably reside in New York, Pennsylvania, or Florida. It is estimated that the New York State Cancer Registry, which began in 1976, currently captures 95% or more of cancers (excluding basal cell skin cancers) diagnosed among residents of New York State excluding New York City.

However, if an increase in cancer is found in a cohort study for which questions remain about the contribution to workplace exposure to chemicals versus non-occupational risk factors of cancer, a follow-up case control study could be considered in which former workers with cancer and a subset of workers without cancer (or their families) were interviewed to obtain additional information on exposure to chemicals at work and non-occupational risk factors for cancer.

If a study is done, we would seek information related to the chemicals used in various jobs from some former IBM employees to supplement the information in company records.

C. COMMENTS IN SUPPORT OF STUDY:

The WBESC supports this study and will seek political support for the funding. The WBESC supports the comments from Dr. Richard Clapp.

The Central New York Labor Federation (AFL-CIO) urges that NIOSH provide funding for the proposed cancer study among former IBM employees who worked at the Endicott, New York facility.

The Western New York Council on Occupational Safety and Health urges that NIOSH provide funding for the proposed cancer study among former IBM employees who worked at the Endicott, New York facility.

The New York State AFL-CIO urges that NIOSH provide funding for the proposed cancer study among former IBM employees who worked at the Endicott, New York facility.

The Central New York Council on Occupational Safety and Health urges that NIOSH provide funding for the proposed cancer study among former IBM employees who worked at the Endicott, New York facility.

Dr. Richard Clapp urges NIOSH to carry out the proposed cancer study among former IBM employees who worked at the Endicott, New York facility.

Marian Feinberg, Environmental Health Coordinator, For A Better Bronx urges that NIOSH provide funding for the proposed cancer study among former IBM employees who worked at the Endicott, New York facility.

Larry Cohen, President, Communication Workers of America, AFL-CIO, urges NIOSH to implement the groundbreaking "Proposed Cancer Study Among former IBM Employees Who worked at the Endicott, New York, manufacturing facility."

Numerous private citizens also expressed support for a study.

D. COMMENTS OPPOSING STUDY

Comment:

Opinion that IBM should pay compensation to employees, rather than spending money on a study.

Response:

The federal government, not IBM, would fund any cohort study conducted by NIOSH.