SIA Worker Health Project

Since the late 1980’s, SIA and its member companies have participated in numerous research efforts to ensure the safety of the wafer fabrication environment and the health of this workforce. An exhaustive, five-year epidemiological study conducted by researchers from Vanderbilt University covering more than 100,000 semiconductor industry workers found no association between overall cancer mortality and working in wafer fabrication cleanrooms. The $7.5 million study was conducted by a team of researchers from the Vanderbilt University Department of Medicine and the Vanderbilt-Ingram Cancer Center. The study was made possible by research grant from SIA. The study findings are detailed in two peer-reviewed articles published in the Journal of Occupational and Environmental Medicine. An abstract can be reviewed at http://journals.lww.com/joem/Fulltext/2010/11000/Cancer_Mortality_Among_US_Workers_Employed_in_5.aspx. In addition, a number of frequently asked questions appear at the end of this summary. The history and status of this research project are detailed below, followed by a history of earlier SIA Worker Health Projects.

History and Status of the Retrospective Epidemiological Study

After the results of a feasibility study, conducted by Johns Hopkins University researchers, concluded that an epidemiology study was feasible, the SIA Board of Directors, at the March 2004 meeting, decided to fund a retrospective cohort epidemiology study to determine if wafer fabrication workers in the semiconductor industry have experienced higher rates of cancer than non-fabrication workers. The independent Scientific Advisory Board (SAB) to the SIA Worker Health Projects, formed in March 2003, has remained involved, as advisors, in all aspects of the retrospective cohort epidemiology study, including the selection of researchers and the design and conduct of the study. A Project Management Committee (PMC), consisting of occupational health and EHS representatives from the participating member companies and SIA and the Project Manager, Chuck Axten, Ph.D., provided internal guidance to the study. Key activities in the planning and conduct of the study have been:

- The SIA PMC prepared and posted a Request for Proposal (RFP) for the epidemiology study on the SIA Website. Additionally, the RFP was advertised in the EpiMonitor and posted on the Duke University Web Server.
- After review of proposals and interviews of investigators by the PMC and the SAB, SIA announced, on August 2, 2005, that it had signed a contract with Vanderbilt University to conduct a retrospective epidemiological study to determine if there is an increased cancer risk among wafer fabrication workers compared to other semiconductor industry workers and the general population. (See Press Release)
- The Key Vanderbilt researchers are:
  - Dr. Joseph McLaughlin- Principal Investigator, Epidemiology
  - Dr. William Blot- Principal Investigator, Epidemiology
  - Dr. John Boice- Project Manager
The multimillion dollar study spanned nearly 30 years of activity.
The study included review of over 100,000 worker records with follow-up for mortality of the cohort through December 31, 2007.
The exposure assessment component classified workers by fab or non-fab worker status and by subcategories of these groups.
The study, which got underway in August 2005, was completed in mid-2010 and underwent an exhaustive peer review process prior to being accepted for publication in the highly respected *Journal of Occupational and Environmental Medicine*.

History of the Research Projects and Activities that preceded the Retrospective Epidemiological Study

In 1999, the SIA undertook an evaluation of existing data to identify if an assessment of risk could be made and whether or not sufficient data was available to perform a retrospective epidemiology study. To perform this evaluation, a Scientific Advisory Committee (SAC) consisting of seven experts in health and industrial hygiene was retained. NIOSH representatives agreed to serve an ex-officio role in this effort. The SAC concluded in late 2001 that there is no affirmative evidence of increased risk of cancer among U.S. semiconductor factory workers. The SAC also reported that insufficient data exists at the present time to conclude whether exposure to chemicals or other hazardous materials has or has not increased such a risk of cancer. *(SAC Executive Summary)*. In 2002, acting on the SAC recommendations and those of the SIA committees supporting this effort, the SIA Board of Directors agreed to support and fund three initiatives as part of a new Worker Health Project:

- A retrospective cohort scoping initiative to evaluate if sufficient data existed to perform retrospective epidemiology;
- A health surveillance initiative to judge if it is feasible to identify a common language for classifying worker information to a common format and to perform a survey of health surveillance activities at non-semiconductor companies;
- A primary prevention initiative to identify ways to provide better chemical and better process information prior to introducing new chemicals into the semiconductor manufacturing workplace.

The status of these projects is as follows:

- A Project Manager, Chuck Axten, Ph.D., was contracted to manage the three initiatives.
An RFP for retrospective scoping initiative was developed and broadly distributed.

Johns Hopkins University was selected to perform the Retrospective Scoping Study.

- Dr. Jean Matanoski- lead investigator for epidemiology
- Dr. Peter Lees- lead investigator for exposure assessment

A Scientific Advisory Board (SAB) consisting of an independent group of prominent scientists in the fields of medicine, industrial hygiene, epidemiology and toxicology was created to provide objective scientific and medical advice to the SIA Worker Health Project Project Management Committee (PMC) for all three initiatives. The SAB is made up of the following scientists:

- Dr. Nurtan Esmen- University of Illinois, Chicago, Industrial Hygiene
- Dr. Grace LeMasters- University of Cincinnati, Epidemiology
- Dr. Gary Marsh- University of Pittsburgh, Epidemiologist
- Dr. David Eaton- University of Washington, Toxicologist
- Dr. Marc Schenker - University of California at Davis, Occupational Medicine
- Dr. Bob Spear- University of California at Berkeley, Industrial Hygiene
- Prior to Dr. Eaton, Dr. Jack Moore served as the toxicologist on the SAB, until his retirement in 2004.

Reports for the two other initiatives were submitted during the first quarter of 2004

- Health Surveillance Initiative - lead investigator, Dr. Don Lassiter
- Primary Prevention Initiative
- New Chemical Introduction - lead investigative team, Weston Solutions
- Opportunities for further reducing potential exposures during equipment maintenance - lead investigative team, EORM
- Results from the Retrospective Scoping Study were reported to the Project Management Committee, the SAB, and subsequently to the SIA Board of Directors in 2004.

- Retrospective epidemiology is feasible
- A meaningful retrospective cohort epidemiology study can be conducted

History of the Reproductive Outcomes Study

In 1989, in response to concerns raised about spontaneous abortion among female cleanroom workers, SIA undertook one of the largest reproductive epidemiology studies ever undertaken by an industry. To oversee the project, a Scientific Advisory Panel (SAP) was selected which consisted of world renowned health and industrial hygiene experts. A representative of NIOSH (the National Institute for Occupational Health and Safety) also participated as an ex-officio member of the SAP. The work, performed by investigators at the University of California, Davis and others, identified that women
working in photolithography and potentially exposed to ethylene-based glycol ethers had a higher risk of miscarriage than women working in other areas of the cleanroom. As a result of this work, the SIA member companies and, eventually, most semiconductor manufacturers worldwide elected to voluntarily phase out ethylene-based glycol ethers from use in photolithography. The results of these studies, including multiple papers, were published in the American Journal of Industrial Medicine in 1995.

Frequently Asked Questions

Q. What was the purpose of this study and why did the industry sponsor it?

A. The purpose of the study was to determine if there is an increased risk of cancer among wafer fabrication workers compared to other semiconductor industry workers and the general population.

The leaders of SIA - senior officials from member companies - recognized that the semiconductor manufacturing process necessarily requires use of potentially hazardous chemicals and materials. These leaders also noted that there have been a number of media articles that raised questions as to whether there has been sufficient scientific analysis to determine whether working in semiconductor manufacturing increases cancer risk to industry workers.

SIA and its member companies have participated in or sponsored a number of research efforts over the past three decades to ensure the safety and health of the industry workforce.

In 2004 the SIA board decided to fund a retrospective epidemiology\(^1\) study to determine whether semiconductor manufacturing workers face a higher risk of cancer when compared to non-manufacturing workers and the general population.

Q. Who conducted this study and how were the researchers selected?

A. The study was conducted by a team of researchers from Vanderbilt University and the Vanderbilt-Ingram Cancer Center.

\(^1\) For a brief summary of what an epidemiology study is, please see the notes at the end of this document.
The research team includes nationally known scientists with expertise in cancer, epidemiology, toxicology, and related disciplines.

The research team was selected through a competitive process involving a detailed request for proposals. The qualifications, experience, and credentials of those who submitted proposals were reviewed by an independent Science Advisory Board (SAB). Requisite qualifications included demonstration of their ability to conduct a study of this type, complexity and magnitude; the availability of a sufficient number of qualified staff; their experience in conducting similar studies; the time frame for conducting the study; and cost.

The SIA board of directors made the final decision to award a research grant to the Vanderbilt University research team.

**Q. How much did the study cost and who paid for it?**

A. The SIA grant to the Vanderbilt University research team amounted to $7.5 million. The funds were provided by SIA member companies.

There were substantial additional costs associated with collecting data and information requested by the researchers and providing access to manufacturing facilities and other logistical support essential to conducting the study. These costs were borne by member companies and were significant but have not been itemized.

**Q. What was done to ensure the independence of the researchers?**

A. The research team designed the study, analyzed and interpreted the data, and wrote the peer-reviewed articles that summarized the study findings.

An independent Science Advisory Board, whose members included experts in epidemiology, medicine, toxicology, and related disciplines, provided technical assistance.
Ultimately, the credibility of any epidemiology study and its conclusions depend on the quality of the study and the integrity, credentials, and reputation of the researchers. The research team at Vanderbilt University is nationally recognized for its capability, integrity, and experience.

**Q. What were the basic findings of the study?**

A. The researchers concluded that: “Work in the US semiconductor industry, including semiconductor wafer fabrication in cleanrooms, was not associated with increased cancer mortality overall or mortality from any specific form of cancer.”²

The researchers also found no evidence of increased mortality from all causes or from all cancers when comparing employees working in cleanrooms to non-fabrication workers.

**Q. How many workers were in the study population?**

A. The study “cohort”³ consisted of more than 100,000 workers employed at two U.S. semiconductor companies between 1968 and 2002. More than 14,000 of the employees in the study population began employment in the semiconductor industry before 1983.

The study population included workers involved in wafer fabrication as well as non-fab jobs, and hourly and non-hourly workers.

**Q. How many companies participated in the study?**

A. All SIA member companies contributed to funding the study. By agreement, the identity of the companies that provided data to the researchers was not reported in the study.

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² To review the complete articles on the summary as published in the *Journal of Occupational and Environmental Medicine* follow this link: [http://journals.lww.com/joem/pages/default.aspx](http://journals.lww.com/joem/pages/default.aspx).
³ Please see the notes at the end of this document for a definition of this term, which is used to describe the specific population involved in an epidemiological study.
The agreement between SIA and the researchers also protects the privacy of the individuals that made up the study population.

Ultimately, the availability of requisite data led the researchers to recommend that the study population be drawn from two companies that they considered to be representative of the workforce of the industry.

Q. Why were workers from only two companies selected for the study population?

A. This was a very complex study. It covered a period of more than 40 years. Researchers needed complete work histories on more than 100,000 workers and sufficient data to create a chemical exposure assessment model. More than 60 different chemicals, 37,000 department and 8,600 job codes were involved in developing the exposure assessment model. Ultimately, the availability of the requisite data led the researchers to draw the study population from two companies.

The study involved site visits to 10 cities in five states with wafer fabrication facilities. Of the total study population of more than 100,000 workers, more than 14,000 workers began employment prior to 1983.

Q. Why did the study focus on cancer mortality (i.e., deaths attributed to cancer) rather than cancer incidence?

A. The limited availability of reliable data on cancer incidence precluded doing such a study.

Q. How did the researchers learn about the causes of death of former employees? Aren’t medical records confidential?

A. Deaths and causes of death were derived from publicly available documents or databases, not from participating companies.

The primary sources for information about deaths were the National Death Index (NDI), Social Security mortality records, and, when needed, death certificates. The NDI, which has records of nearly all deaths and causes of death, was established specifically to facilitate studies by medical researchers. The NDI is not accessible to companies or the
general public – a researcher must have a legitimate reason to access NDI data and must formally apply. Using identifiers such as name, social security number, and date of birth, researchers can in most cases determine the health outcomes for individuals, even years after they may have left participating companies.

Q. Will the industry sponsor a follow-up study?

A. The researchers noted that the study population had a relatively low average age and an associated relatively low number of deaths among the study population. They concluded that regular mortality updates of the study population are warranted.

The industry will continue to support activities that will ensure the safest possible work environment for employees. If there is a reason in the future to consider another study or a follow-on study, the SIA board will make a decision based on the best information available to it at that time.

Q. Describe some of the ongoing activities of the semiconductor industry to address worker health and safety issues.

A. The semiconductor industry is working on a worldwide basis to support a number of initiatives on environmental, health, and safety issues. SIA and member companies have taken a leadership role in these efforts that include:

- Continuously seeking chemicals that present the fewest risks to its workforce and managing any potential risks through effective engineering controls;
- Re-designing processes to use smaller amounts of chemicals and to use chemicals that are less hazardous to human health and the environment wherever possible.
- Developing new tools and equipment to isolate employees from exposure to chemicals that could potentially pose health risks;
- Developing engineering controls to eliminate exposures (exhausts, interlocks, isolation of materials);
- Installing continuous monitoring devices where necessary and appropriate;
- Retaining highly skilled professionals to design, implement, and manage comprehensive safety and industrial hygiene programs and procedures;
- Making chemical information more readily accessible to workers;
Implementing engineering or administrative controls that eliminate any exposures and minimize the need for personal protective equipment.

Many of these activities entail significant investment in capital equipment, research and development, and human resources. Working through the World Semiconductor Council, SIA and its counterparts in Europe, Japan, Korea, China, and Chinese Taipei share information on best practices and coordinate efforts to achieve continuous improvement in EHS programs.

**Q. Have there been other studies of cancer in the semiconductor industry?**

A. There have been two other recent epidemiology studies of employees in the semiconductor industry. The University of Alabama-Birmingham conducted a cancer mortality and cancer incidence study of IBM employees at two large semiconductor facilities. The Health and Safety Executive (HSE) in the United Kingdom conducted a cancer mortality and incidence study of a National Semiconductor wafer fabrication facility in Scotland and updated the study in 2010. The findings of these studies were reassuring in not finding evidence of an increased cancer risk associated with working in wafer fabrication. Both studies produced results that were consistent with the findings of the Vanderbilt study. When, as in this situation, the findings of several epidemiologic studies of different populations are consistent with one another, it strengthens the confidence in the conclusions of the studies.

**Notes**

1) Epidemiology is the branch of medicine that deals with the causes, distribution, and control of diseases in populations. Epidemiologic studies attempt to identify, measure, count, and control causes of untimely deaths. Such studies are based on comparisons of different groups of people. These studies provide information about the occurrence of disease in a population or its subgroups over time. Data sources include death certificates, special disease registries, surveys, and population censuses.

2) The *Journal of Occupational and Environmental Medicine* is the official publication of the American College of Occupational and Environmental Medicine. The publication carries peer-reviewed, in-depth research articles and technical reports to keep occupational and environmental medicine specialists up to date on new developments in the prevention, diagnosis, and rehabilitation of environmentally induced conditions and work-related injuries and illnesses.

3) The term “study cohort” refers to a well-defined group of subjects or patients who have had a common experience or exposure and are then followed up for the incidence of diseases.