



# PSP 2017: A voluntary *product stewardship program* (PSP)

2021 - Fifth Annual Report by HTIW Coalition to the *Occupational Safety and Health Administration* (OSHA)

*Data-Pro Consultants, LLC*
on behalf of HTIW Coalition

*PSP 2017:*
*A voluntary product stewardship program (PSP)*
*For High Temperature Insulating Wools Fifth Annual Report*

***Submitted to:***

**The *Occupational Safety and Health Administration* (OSHA)**

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# PSP 2017: A voluntary product stewardship program (PSP) for High Temperature Insulating Wools

## Introduction

The manufacturers of *refractory ceramic fiber* (RCF)[1] and other *High Temperature Insulating Wools* (HTIW) are committed to protecting the health and safety of their employees and those of their customers. In the United States, these companies are represented by the HTIW Coalition.[2] The primary objective of this organization is to develop and disseminate guidance on appropriate work practices and other occupational safety and health measures in the production and use of HTIWs.

The HTIW Coalition and its member companies have a successful track record of full cooperation with several US government agencies. Among many initiatives, the HTIW Coalition developed a voluntary[3] *product stewardship program* (PSP) with oversight by the US *Occupational Safety and Health Administration* (OSHA).

This is the fifth annual report to be submitted to OSHA pursuant to the HTIW's latest PSP, named "PSP 2017." Reports prepared subsequent to years one through four were shorter (abridged) reports, suitable for a wider distribution to OSHA Regional and Area offices and others seeking a high-level overview of the program.


PSP 2017 is the fourth iteration of the industry's voluntary PSP with OSHA oversight and extends previous programs initiated in 2002, 2007 and 2012. PSP 2017 builds upon the success of earlier iterations of the program (PSP 2012 (in place from 2012 to 2016), PSP-HTW (2007-2012) and PSP 2002 (2002-2006)). Prior to 2002 the

[1] RCF belongs to a class of materials called *synthetic vitreous fibers* (SVFs), which also includes fiberglass and mineral wool. RCF is also a type of *high temperature wool* (HTW). RCF is more properly termed *aluminosilicate wool* (ASW), but the term RCF is more commonly used in the United States.

[2] In prior years, HTIW Coalition was known as *Refractory Ceramic Fibers Coalition* (RCFC). For more information, see the coalition website at http://www.htiwcoalition.org/.

[3] This program differs from other voluntary OSHA programs, such as the Voluntary Protection Program (VPP). Among other differences, participation in PSP 2017 does not confer any immunity from OSHA inspections. In fact, each of the HTIW Coalition full members has had one or more inspections during the course of the PSP.

industry conducted a similar program with oversight by the US *Environmental Protection Agency* (USEPA).

Over the years, these stewardship programs have been deemed valuable by OSHA, NIOSH and industry.[4]

PSP 2017, which runs from 2017 through and including 2021, includes most of the features of PSP 2012, modified as appropriate to reflect lessons learned in this and earlier programs.

Based on the success of the previous PSP programs and the continued desire to manage possible occupational risks in the manufacture and use of RCF, HTIW Coalition and its member companies will meet with OSHA on May 4, 2022 to confirm the extension of the previous program to a fourth five-year program called PSP 2022.

This fifth annual report under the present agreement covers the complete five-year period with special emphasis on developments in 2021.[5] This report was written on behalf of the HTIW Coalition by *Data-Pro Consultants LLC* (Data-Pro), for submission to OSHA and distribution to other interested agencies and organizations.

"OSHA expects the PSP will provide continuous improvements…and the periodic reports will demonstrate that companies are fulfilling the provisions of the PSP. It is with this optimism and gratitude for your efforts that OSHA reaffirms its support…"
Loren Sweatt,
Deputy Asst. Secretary for Occupational Safety and Health, 24 October 2017

## HTIW Coalition Members

Members of the HTIW Coalition when PSP 2017 was signed included Morgan Thermal Ceramics (http://www.morganthermalceramics.com) and Alkegen (formerly Unifrax 1 LLC) (http://www.alkegen.com/).

"The [NIOSH] partnership with RCFC has led to the development of…more effective engineering controls and improved work practices"
NIOSH website

[4] See e.g., Waugh, R. A., (2002), PSP 2002, A Partnership to Succeed. *Insulation Outlook*, July 2002. More recently, see the letter from OSHA Deputy Assistant Secretary, Loren Sweatt, to HTIW Coalition, dated October 24, 2017, available online at: http://www.htiwcoalition.org/documents/Letter%20from%20OSHA%20to%20HTIW%20Coalition%20for%20PSP%202017.pdf. NIOSH comments are available online at: https://www.cdc.gov/niosh/programs/manuf/partners.html

[5] When the US General Accounting Office examined OSHA's voluntary compliance strategies (see http://www.gao.gov/new.items/d04378.pdf), it concluded that results were promising, but noted that some partnerships did not submit evaluation reports. This report is comprehensive and addresses all elements of PSP 2017.

Alkegen and Morgan Thermal Ceramics are major producers of RCF and other high temperature refractory materials in the United States and in many other countries of the world.

Two other North American RCF manufacturers were associate members of the HTIW Coalition when PSP 2107 was developed; both became full members of the Coalition in October 2021:

- Nutec, headquartered in Coahuila, México joined the HTIW Coalition as an associate member in 2008. Nutec produces RCF and low biopersistence insulating products at a plant in México and has sales offices and distributors in 49 countries of the world (see http://www.nutec.com/). In 2016 Nutec opened a plant in Huntersville, North Carolina to manufacture RCF products and low biopersistence insulating products for the US and Canadian markets.
- HarbisonWalker International (formerly ANH Refractories Company) also joined the HTIW Coalition as an associate member in 2008 (see http://www.thinkhwi.com). HarbisonWalker International is headquartered in Pittsburgh, PA, and manufactures RCF at its Pryor, OK, plant. HarbisonWalker International and its affiliates distribute RCF and other refractory products throughout North America, and have significant sales worldwide.

With the inclusion of Nutec and HarbisonWalker International in the HTIW Coalition, 100% of the North American producers of RCF are represented. The global reach of RCF stewardship efforts now includes Europe, North America, Australia and several countries in Latin America and Asia.

The members of the HTIW Coalition work closely with the European association of HTIW named ECFIA (http://www.ecfia.eu/). ECFIA members[6] operate a similar product stewardship program named CARE, an acronym for its objective to *Control And Reduce Exposure*. The

[6] See https://www.ecfia.eu/about-members-partners/ for a list of members.

CARE[7] Program includes the same features as PSP 2017, including exposure monitoring at plants owned by ECFIA members and at customer facilities throughout Europe.

Representatives from OSHA have been invited to an annual briefing where a summary of program developments in 2021 will be presented.

## COVID-19 Pandemic: Impacts On PSP 2017 Monitoring In 2021

One of the major components of PSP-2017 is collection of workplace monitoring samples at internal HTIW Coalition member plants and customer plants. The outbreak of the novel Coronavirus disease (COVID-19) resulted in a worldwide pandemic in 2020 and 2021 that severely affected business activity. US Government actions to mitigate spread of the disease included lockdowns (stay in place orders), travel restrictions, quarantine requirements[8] for persons entering many states, social distancing and face mask requirements. These actions, while necessary to control the spread of COVID-19, made workplace monitoring difficult or impossible throughout much of 2020 and 2021. The impact on monitoring at customer facilities has been more severe than at internal facilities, as discussed below.

**Internal Monitoring**: After the first quarter of 2020, HTIW Coalition members and associate members experienced reduced demand for products as a result of the economic slowdown, and many workers were laid off or furloughed as production declined. The reduced numbers of active employees meant that there were fewer workers to monitor, and fewer *Industrial Hygienists* (IHs) were available to collect samples. Also, social distancing requirements that were imposed to reduce the spread of COVID-19 (i.e., maintaining a distance of six feet between workers) made attaching monitoring equipment to workers difficult. Some IHs experienced increased resistance from workers selected to be monitored after March 2020 (workers expressed concern about maintaining social distancing throughout the monitoring event, and were reluctant to participate). COVID-related restrictions were gradually relaxed in 2021, but the impact on sample collection persisted at many facilities.

A consequence of these problems was reduced sample collection in some *functional job categories* (FJCs) at internal plants early in 2021. In order to make sampling goals realistic, monitoring targets were reduced by a ratio equal to the current headcount divided by the pre-COVID headcount at each plant (the target reduction ratio was updated each quarter). Late in the year these adjustments were no longer required, and, by year-end, HTIW Coalition member companies were able to *exceed* the total internal sample target (339 samples collected against a target of 300 samples, including samples contributed by associate members (as noted above, Nutec and HarbisonWalker International are full members going forward). Some internal FJC subgoals were not achieved (in the Finishing and Other (NEC) FJCs), but percent achievement in these FJCs was high at 90% to 95%.

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[7] See https://www.ecfia.eu/support-exposure-control/ for details.

[8] Persons entering many states were required to quarantine for two weeks before traveling freely within the state. Many states maintained lists of other states with high numbers of COVID-19 cases; visitors from states on these lists were asked to self-quarantine for a period of time (typically 10 days to two weeks).

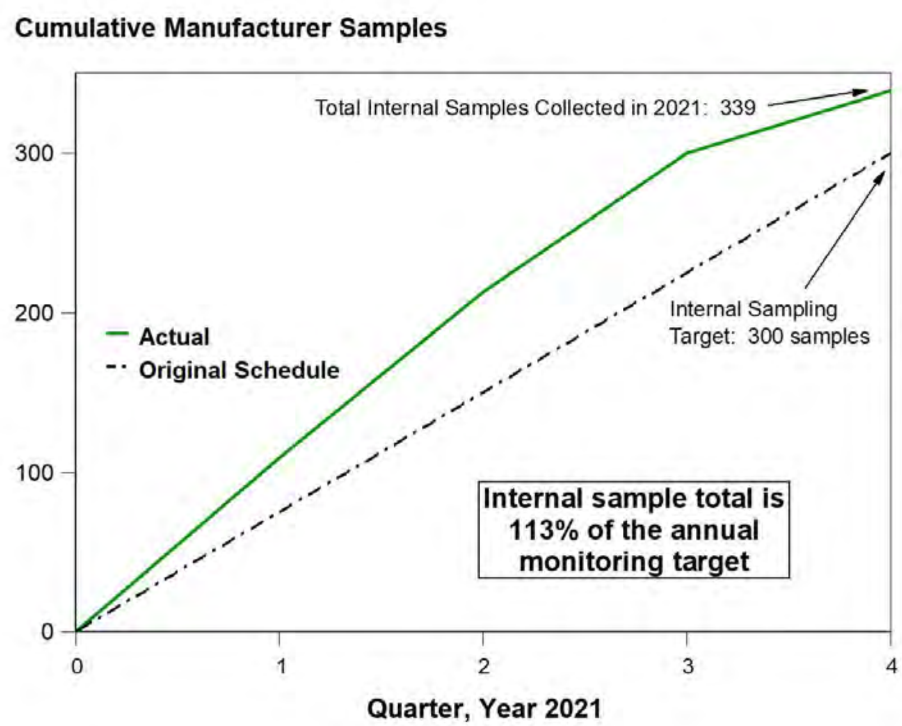


**FIG. S-1.** *Cumulative internal sample collection in 2021.*

Figure 1 illustrates sample collection at internal plants throughout 2021. Note that sample collection was ahead of schedule throughout the year, but due to worker shortages at some plants the targeted mix of FJCs was not achieved in some cases (details are given later in this report). By year-end, HTIW Coalition members had collected 339 internal samples (39 samples over the internal sampling target of 300).

**Customer Monitoring:** Customer monitoring in 2021 presented greater challenges compared to monitoring at internal plants. Internal plants generally have on-site personnel who collect the workplace samples; no travel is required to conduct monitoring. In contrast, customer monitoring usually requires air travel and remote lodging in order to conduct a monitoring visit. Early in 2021, lockdowns, travel restrictions and quarantine requirements made customer visits very difficult or impossible in some regions of the country. As the year progressed, restrictions were gradually relaxed, and customer visits were possible. Yet some resistance to monitoring visits persisted, and the pace of customer visits was substantially reduced compared to pre-COVID years.

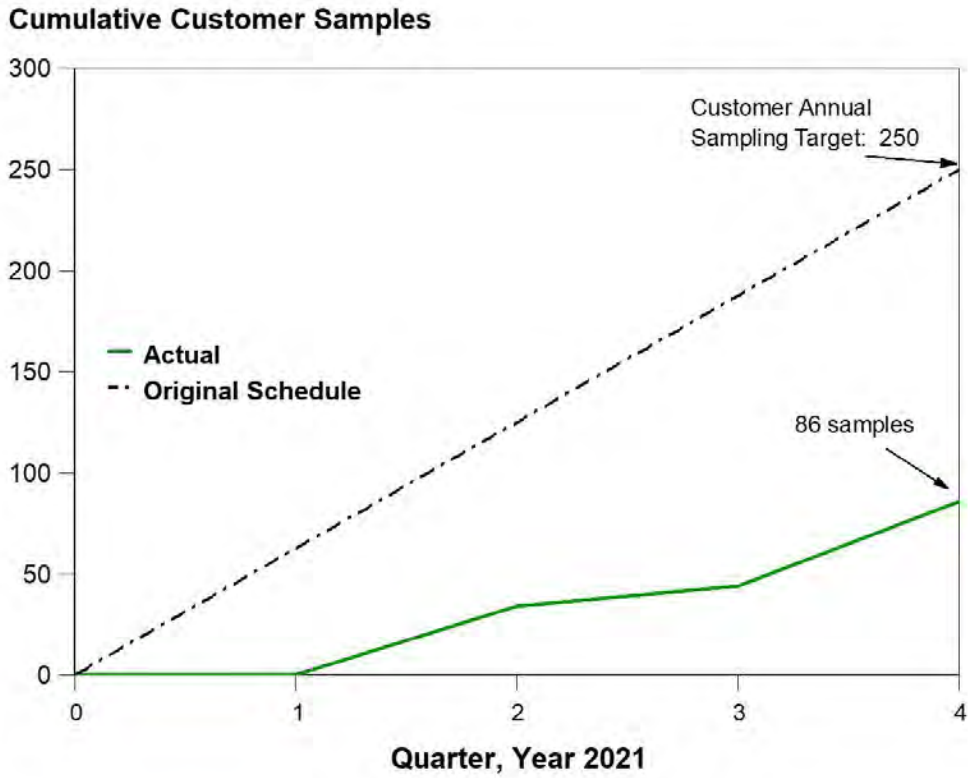


**FIG. S-2.** *Cumulative customer sample collection in 2021.*

Figure S-2 illustrates sample collection at customer facilities in 2021. No samples were collected in the first quarter as a result of the restrictions discussed above. The 86 customer samples collected in 2021 was substantially below the target of 250 samples, representing about 34% achievement. This achievement is marginally better than observed in 2020 (29%). As the remaining COVID-related restrictions are relaxed, HTIW Coalition anticipates the pace of customer sample collection will improve.

HTIW Coalition and its members remain committed to achieving workplace sampling targets.

## Stewardship Program Scope

Before summarizing program results for 2021, it is appropriate to describe briefly the overall PSP 2017 program scope, which has remained essentially the same[9] over the years.

Table S-1 provides a high-level overview of the eight major components (exposure monitoring, medical monitoring, development of improved workplace controls/practices, specification of respirator required jobs and other elements of a respiratory protection program,

[9] There have been some changes in the program at a detailed level (based on lessons learned), but the overall scope has not changed.

worker training, product research, environmental responsibility, and the development of an efficient communication strategy) included in this multi-faceted stewardship program.

**TABLE S-1.** *Major components and elements/features of PSP 2017.*

| Component | Elements/features |
|---|---|
| **Exposure monitoring at HTIW Coalition member and customer facilities** | Verify attainment of the recommended exposure guideline (REG)<br>Assess determinants of exposure<br>Track exposure trends<br>Benchmarking |
| **Medical monitoring/ health effects research** | Continuing medical surveillance of current workers<br>Continuing mortality study of present and former workers |
| **Workplace controls/practices** | Search for improved engineering controls and workplace practices to reduce occupational exposure |
| **Respirator use** | Ensure appropriate respirators are used for those jobs/tasks where feasible engineering controls and workplace practices do not ensure compliance with the REG |
| **Training** | Provide training sessions for employees of HTIW producers, customers, and others |
| **Product research** | Encourage research to develop improved understanding of determinants of fiber toxicity |
| **Environmental responsibility** | Minimize consumption of natural resources, reduce waste generation, and conserve energy. |
| **Communications** | Disseminate PSP results to key stakeholders<br>Provide Annual Reports to OSHA |

## *Detail on PSP components*

**Exposure monitoring** is conducted at both HTIW Coalition member plants and customer facilities using a statistically designed *stratified random sampling plan* (SRSP). *Time weighted average* (TWA) fiber concentrations are measured on workers doing various jobs on various forms of RCF. The SRSP is designed to provide accurate estimates of weighted average fiber concentrations for a fixed total sample size. The purposes of this monitoring are to:

- Verify attainment of the program's *recommended exposure guideline* (REG) of 0.5 *fibers per cubic centimeter* (0.5 f/cc) for RCF,[10] and applicable *occupational exposure limits* (OELs),
- Present *objective data* on occupational exposure (with and without correction for the protective effect of respirators) to RCFs,
- Measure time trends in worker exposure,
- Provide relevant data for benchmarking, and to
- Learn more about the determinants of exposure.

To date the exposure database includes more than 31,600 personal monitoring observations (time weighted average fiber concentration measurements[11]) collected in the United States, Europe, and a number of other countries globally. Customers to be monitored include both those selected at random ("selectees") and those who specifically request monitoring ("volunteers").[12] A typical monitoring visit entails a "walk around" observation, worker training, exposure monitoring, and finally an exit interview. Monitoring results and any recommendations are included in a visit report provided to the customer by the HTIW Coalition member collecting the monitoring data.

Insulating fibers are made in various forms, including bulk fiber, blanket, modules (folded blanket with attachment hardware to facilitate installation in industrial furnaces), vacuum formed shapes, putties, paper, felt, and textiles. Exposure sampling includes all of the unit operations and processes associated with these product forms.

Beginning in 2017, the HTIW Coalition voluntarily increased the annual sampling target for internal plants from 250 to 300 TWA samples. This change was made in order to maintain the targeted precision of the weighted average fiber concentration estimate.

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[10] The REG was developed on the basis of prudence and technical feasibility, not demonstrated risk. NIOSH prepared a comprehensive criteria document in 2006 that established a *recommended exposure limit* (REL) that is numerically equal to the REG (see https://www.cdc.gov/niosh/updates/upd-06-12-06.html).

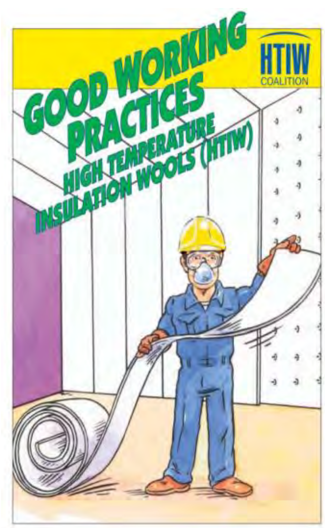
[11] Each observation, which may involve the analysis of samples from several cassettes, also records data on many other ancillary variables, including the sector, job, type of fiber, use of respirators (and make and model), and types of controls in place.

[12] Statistical analyses indicate that exposures are similar within each of these two groups.

**Medical monitoring/health effects research** is another key component of the PSP. Medical surveillance is conducted at HTIW Coalition member plants to inform workers of possible health effects of occupational exposure to RCF. The *University of Cincinnati* (UC) and other researchers have completed and reported in peer-reviewed literature morbidity studies of occupationally exposed workers. A mortality study of occupationally exposed workers continues at UC.

**Workplace controls/practices** include use of exposure monitoring and other data collected to identify efficient engineering controls and workplace practices. Data used to help identify and develop improved controls includes monitoring data collected as part of the statistical sampling plan according to a specified protocol (historical baseline samples) plus another group, termed *special emphasis samples*[13] (SES), used for the assessment and optimization of engineering controls and work practices.

PSP 2017 embraces the traditional hierarchy of controls to achieve compliance with the REG with first priority given to feasible and effective engineering controls and work practices. However, it is recognized that some tasks/jobs require respiratory protection to ensure that exposures are reliably beneath the REG. HTIW Coalition members comply with OSHA requirements and NIOSH recommendations and share useful information with customers.




**Training** is an important component of PSP 2017. Training is provided to employees of HTIW Coalition member companies and also to customers and other interested parties. Methods for delivery of this training vary from "toolbox" or "tailgate" training sessions to more formal workshops and seminars. In many cases, formal and informal training sessions are presented at customer visits for collection of workplace monitoring data. A workshop was held in June 2015 for *industrial hygiene* (IH) personnel from both the United States and Europe to help ensure uniformity of reporting and reemphasize the commitment of RCF producers to the PSP. Similar follow-on training sessions were held as needed over the course of PSP 2017 as an introduction to the program for newly hired IH personnel, and as refresher training for experienced workers.


PSP 2017 includes a **product research component**. In the context of HTIW development the aim of research is to support the "3Ds" paradigm (dose, dimension, and durability). The objectives of this effort are to avoid or decrease any

[13] Special emphasis samples are in addition to the 31,600 baseline monitoring samples reported above. We estimate that approximately 2,500 SES have been collected in addition to the baseline samples.

potential hazards and avoid developing products that increase the potential compliance burden for customers or end-users.

**Environmental responsibility** is a catch-all category used to denote efforts to minimize consumption of raw materials, conserve energy, and minimize waste generation rates by increasing process yields, recycling, and other means.

**Communications** are a key component of PSP 2017. This component includes the development of a variety of media presentations for various audiences ranging from "cartoon books" (available in several languages from both the HTIW Coalition and ECFIA) describing recommended handling practices to articles in peer-reviewed technical journals. It also includes brochures, reports, and video clips on improved handling practices, *safety data sheets* (SDS) and reports to OSHA.

Though not formally part of PSP 2017, the monitoring program also includes *alkaline earth silicate* (AES) wools and *polycrystalline wools* (PCW) in addition to RCF.

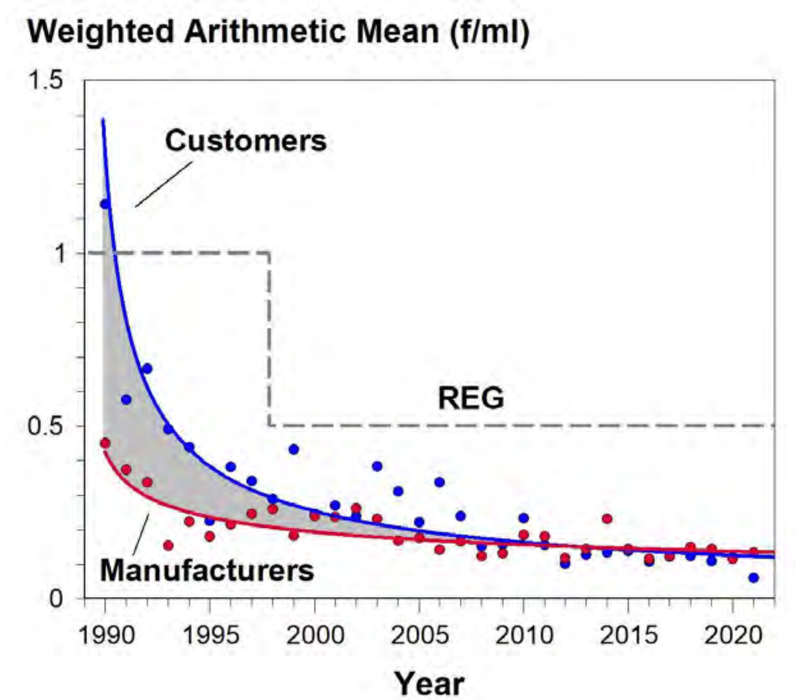



**FIG. S-3.** *Time trends in weighted average TWA concentrations at manufacturer and customer facilities.*

## Key Results

Some of the PSP 2017 components have numerical targets. As discussed above, *COVID-19 restrictions prevented achievement of the numerical sample target for customers; sample collection for internal plants exceeded the target.* Table S-2 (placed at the end of this section) summarizes achievements in 2021 for the various PSP 2017 components. The main body of the report provides additional detail.

Results of the exposure monitoring program in 2021 indicated that:

- Aggregate sample collection targets were exceeded at HTIW Coalition member plants; COVID-19 restrictions prevented collection of customers samples for much of the year,
- RCF manufacturers and customers continue to demonstrate high rates (98-100% including the effects of respirators) of compliance with the industry's REG,
- Weighted average TWA concentrations at both fiber producers and customers have decreased substantially since the integrated industry-wide program began. Figure S-3 shows a time trend of weighted average exposures at manufacturers and customers

from 1990 to 2021. (The weighted average concentrations plotted in Fig. S-3 [measured in units of fibers per milliliter, f/ml] do not take into account the protection provided by respirators, if worn. Weights used in computing the weighted average fiber concentration are equal to the proportion of workers in each of eight FJCs.) Although the overall trend shown in Fig. S-3 is one of decreasing exposures, there is scatter about this trend with occasional 'upticks' and recoveries. Exposures at manufacturers experienced an uptick in 2014 and the weighted average exposure was greater than the predicted value based on the long term trend. Although similar excursions have occurred in the past, RCF producers examined the exposure data closely to identify which plant-process combinations have experienced increases and to determine whether there were assignable causes for any exposure increases. At some facilities, increases were attributable to unique (and probably non-recurring) circumstances. At others, it appears that the capacity of engineering controls did not keep pace with fiber production or throughput and plans were developed and implemented to increase the capacity of controls.

- Coalition members were mindful of the 2014 uptick and implemented several physical plant upgrades and/or administrative programs to get things back on track. For example, in 2015:
  - Morgan Thermal Ceramics implemented major local engineering control improvements at two manufacturing facilities in the form of new or additional dust collectors at fiber handling stations, several new booth-style dust filtration systems, improved ductwork and new exhaust hoods at fiber cutting stations, and a new water jet cutter. These improvements were made in response to the need for increased engineering controls associated with increased fiber production and to reduce airborne dust concentrations.

  - Alkegen added controls and also developed a new green-amber-red (GAR) action plan to provide feedback. Under this plan fiber concentrations above the REG (red observations) are reported directly to senior management as well as IH and plant personnel; those beneath the REG but at or above the 95th percentile (amber observations) are reported to IH and plant personnel for investigation; and those not fulfilling either of these conditions (green observations) are viewed as being "in control." The intent of the GAR model is to ensure that exceptional results have increased visibility and to provide more rapid feedback of monitoring results so that the search for corrective actions can proceed expeditiously.
- As shown in Figure S-3, the actions taken by HTIW Coalition member companies have reduced the overall weighted arithmetic mean fiber concentration to values consistent with the long-term trend for the entire duration of PSP-2017 (2017-2021). Continuous improvement under the PSP remains an objective.
- Historically, weighted average TWA concentrations at customer facilities were somewhat higher than those at manufacturers in part because they engage in certain higher-exposure jobs (such as installation and removal of after-service furnace insulation) that are not performed by fiber producers. ***But the differences in weighted***

***exposures between manufacturers and their customers have grown smaller over the years—a key indicator of the success of the PSP as lessons learned by RCF producers are shared with their customers.***

- The weighted average fiber concentration trend data suggest a diminishing returns situation as progress in reducing weighted average exposures has slowed over the years. Fiber producers believe after more than 30 years of research that they have a good understanding of the determinants of exposure for all jobs and have developed effective engineering controls for most jobs. The high rate of compliance with the industry REG noted above attests to this. Jobs can be partitioned as follows:
  - Many jobs already have exposures well beneath the industry's REG and are well controlled.
  - Some jobs, such as mixing/forming (particularly mixing) have exposures closer to the REG and effective controls (such as local exhaust ventilation and closed tank tops) are known. The industry continues to share this knowledge with customers.
  - A few jobs, such as certain finishing operations, have higher exposures that can be reduced with additional controls, such as greater use of local exhaust ventilation (LEV). Respirators are used selectively for these applications and work continues to find better control options.
  - And finally, certain jobs (typically removal of after-service insulation) have high exposures that cannot readily be reduced with engineering controls (even though this has been a subject of continued study over the years). Use of respirators is required for these jobs.
  - Notwithstanding the flattening of the exposure trends, there has been significant progress in reducing exposures over the years, which has materially reduced the cumulative exposure of workers employed in this industry compared to what would have occurred without the PSP. Figure S-4 shows (for both manufacturer (internal plants) and customer (external plant) measurements, see the shaded areas) that the

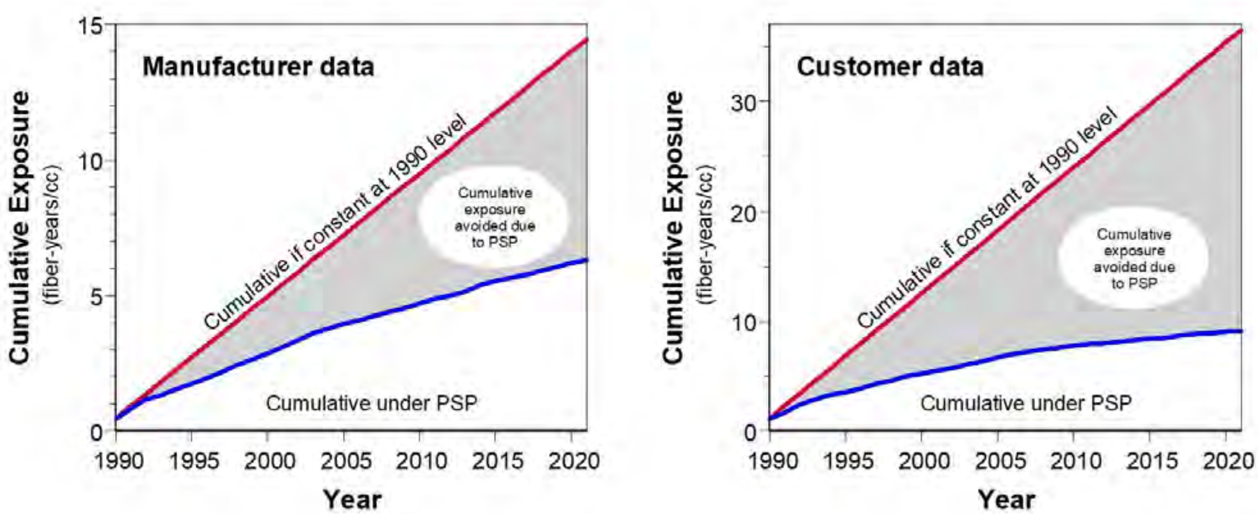



**FIG. S-4.** *Graphs demonstrate cumulative exposure avoided by implementing the PSP program versus continued uncontrolled exposure at 1990 levels for manufacturer (internal) plants (left) and customers (external plants) (right).*

cumulative exposure of either the manufacturer or customer cohorts (beginning in 1990 when the first integrated industry-wide stewardship program was developed) would have been substantially larger but for the exposure reductions brought about by the product stewardship program. The general shapes of these curves will remain the same even if there are no further exposure reductions.

## Health Effects Studies

Over the years the HTIW industry has sponsored numerous studies on RCF toxicology (e.g., animal studies and studies of relevant physical properties) and epidemiology (morbidity and mortality). As well industry scientists and consultants continue to monitor the peer-reviewed scientific literature to learn more about possible health effects associated with exposure to RCF. Of particular relevance, the industry has sponsored a series of studies of morbidity and mortality of RCF-exposed cohorts conducted by University of Cincinnati researchers. Earlier epidemiological studies of cohorts occupationally exposed to RCF concluded that the prevalence of respiratory symptoms (LeMasters *et al*., 1998[14]) and interstitial changes (Lockey *et al*., 2002[15]) was similar to that found in other dust exposed populations. Studies also reported that there was a statistically significant association between RCF exposure and pleural plaques (Lockey *et al.,* 2002).

A key component of the epidemiological studies is an ongoing mortality study. When updated in 2017[16] the authors indicated that results were consistent with earlier findings; there were pleural plaques, no interstitial fibrosis, and no increased lung cancer cases. The excess of cancers of the urinary organs persisted (for those with the highest exposure), but there was significant co-exposure to tobacco and carcinogenic chemicals. One death attributed to mesothelioma (unconfirmed tissue pathology diagnosis) was identified in a worker reporting asbestos exposure.

The most recent mortality report update from University of Cincinnati investigators is now in press and available online.[17] The results remain consistent with prior studies with no significant association with all causes, all cancers, or lung cancer. The increased elevation of malignancies of the urinary organs in the highly exposed workers was again seen, although at least six of the nine workers with urinary cancers were smokers and several had exposures to chemical carcinogens in the workplace. A second employee currently living with a pathologically confirmed mesothelioma

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[14] LeMasters, G. K., *et al.*, (1998). An industry-wide pulmonary study of men and women manufacturing refractory ceramic fibers. *Am. J. Epidemiol*., 148: 910-919.

[15] Lockey, J. E., *et al*., (2002). A longitudinal study of chest radiographic changes of workers in the refractory ceramic fiber industry. *CHEST*, 121: 2044-2051.

[16] LeMasters, G. K., *et al*., (2017). A thirty-year mortality and respiratory morbidity study of Refractory Ceramic Fiber workers. *Inhal. Toxicol*., 29(10): 462-470.

[17] LeMasters, G. K., *et al*., (2022, in press). Mortality of workers employed in refractory ceramic fiber manufacturing: An update. *J. Appl. Toxicol.* (https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/full/10.1002/jat.4295)

was identified, but the SMR was non-significant when both were included in the analyses. The association of these two mesothelioma cases with RCF exposure alone is unclear because of past significant asbestos exposure. This latest update is particularly relevant as the cohort has aged and the time since first exposure for cohort members has increased, making it possible to learn more about the likelihood of diseases with longer latencies.

The main body of this report provides more detail about the 2022 University of Cincinnati results.

## Concluding Comments

As noted above, this is the fifth (and final) report under the present PSP agreement with OSHA. Manufacturers of RCF have learned a great deal from the results of the ongoing PSP and believe that there is value in continuing this program.

**TABLE S-2.** *PSP 2017 Fifth Year achievements.*

| ***Goal(s)*** | ***Tasks*** | ***Fifth Year Achievements*** |
|---|---|---|
| | ***Work Practices:*** | |
| To encourage all manufacturers, customers and end-users to follow proper work practices when handling RCF products. | • Update and communicate HTIW Coalition recommendations for the proper handling of RCFs and cost-effective engineering controls (ongoing).<br>• Promote HTIW Coalition training aids for the proper handling of RCFs (ongoing).<br>• Communicate "Best Practices" for work tasks with elevated airborne fiber concentrations (ongoing). | • Ongoing.<br>• Ongoing.<br>• Ongoing. |
| | ***Worker Training:*** | |
| To develop focused training materials.<br><br>To provide information to customers and end-users regarding potential occupational hazards, appropriate work practices and exposure controls. | • HTIW Coalition and its members will continue to develop and refine standardized employee training aids, including new aids such as on-line training techniques (ongoing).<br>• HTIW Coalition members commit to conduct PSP training sessions when requested.<br>• The PSP 2017 Five-Year Report will contain information about the training sessions conducted, including the number of people trained, videos, brochures and other material distributed during training. | • Ongoing.<br>• 11 training sessions were held to train 83 people at customer facilities including contractors and distributors working with RCF.<br>• 319 training sessions were held to train 3,058 people at domestic manufacturing facilities.<br>• Total training: 330 reported sessions; 3,141 people trained. See text in ***Worker Training*** and ***Customer Service Activities*** sections, and summarized above.<br>• A summary of training over the 5-year PSP program is included in this report. |

**Note:** Tasks taken from the PSP 2017 program documents.

**TABLE S-2 (cont'd.).** *PSP 2017 Fifth Year achievements.*

| *Goal(s)* | *Tasks* | *Fifth Year Achievements* |
|---|---|---|
| | ***Medical Monitoring:*** | |
| To ensure exposed RCF manufacturing workers are evaluated for the potential manifestation of fiber exposure-related health effects.<br><br>To improve customer awareness of the medical surveillance requirements of OSHA's respiratory protection standard. | • HTIW Coalition member companies will maintain a medical monitoring program for their workers producing RCF (ongoing).<br><br>• HTIW Coalition member companies will inform end-users about the key elements of HTIW Coalition medical surveillance program (ongoing). | • HTIW Coalition members have continued the medical monitoring program. See section titled on ***Medical Monitoring*** in text. Additionally, the epidemiology study (mortality) is ongoing.<br><br>• Ongoing. |
| | ***Exposure Monitoring:*** | |
| To evaluate and improve the relative understanding of workplace exposures.<br><br>To facilitate informed decisions regarding improvements in exposure management, including the use of respiratory protection.<br><br>To focus resources upon prioritized initiatives to reduce occupational exposures to airborne fiber. | • Continue to evaluate existing exposure monitoring data to identify targets of opportunity to improve exposure management (ongoing).<br>• Continue monitoring at manufacturing facilities [TARGET: about 300 (8-hr. TWA) samples annually] to address employee RCF exposure and to support the epidemiology study (ongoing).<br>• Continue exposure monitoring at customer facilities [TARGET: about 250 (8-hr. TWA) samples annually] to: (1) provide feedback; (2) track exposure trends (ongoing).<br>• Identify specific job tasks/situations for exposure monitoring using various sampling techniques to (1) evaluate the relative effectiveness of RCF control options, (2) facilitate RCF exposure reductions (ongoing).<br>• Data, analysis, and findings shall be compiled in the PSP 2017 interim annual reports and the five-year reports and shared with OSHA and other interested parties. | • Ongoing. See discussion in section titled ***Exposure Monitoring***.<br>• 339 samples were collected in 2021 from manufacturing facilities. Seven area samples were collected from manufacturers in 2021. 12 *Special Emphasis Samples* (SES) were conducted in 2021 at manufacturing plants.<br>• 86 samples were collected in 2021 from customer facilities. No area or *Special Emphasis Samples* (SES) were collected at customer facilities in 2021.<br>• Ongoing. See ***Exposure monitoring*** section.<br>• Included as part of this annual report in the ***Exposure Monitoring*** section. |

**Note:** Tasks taken from the PSP 2017 program documents.

**TABLE S-2 (cont'd.).** *PSP 2017 Fifth Year achievements.*

| ***Goal(s)*** | ***Tasks*** | ***Fifth Year Achievements*** |
|---|---|---|
| | ***Quality Assurance / Quality Control:*** | |
| To provide independent validations of exposure monitoring program results. | • HTIW Coalition has prepared and adopted a quality assurance plan which it will continue to use (ongoing).<br>• HTIW Coalition members will continue to utilize qualified independent auditors as a mechanism to evaluate fiber sample collection techniques (at manufacturer and customer plant sites).<br>• HTIW Coalition will require laboratories conducting fiber analysis (currently Clayton Laboratories) to annually provide evidence of its certification or other qualification (ongoing).<br>• HTIW Coalition member companies will address any corrective measures required as a result of audit findings (ongoing). | • Ongoing, see ***QA/QC*** section of the report.<br>• One audit at a manufacturer facility was conducted for 2021. The report is included in Appendix B and discussed in the QA/QC section of the report.<br>• No discrepancies were reported by the auditors, therefore no corrective actions taken.<br>• No corrective measures required with sampling procedures. |
| | ***Customer Service Activities:*** | |
| To determine "best" work practices, engineering controls and process controls.<br><br>Follow-up on the best practices commitments made earlier and communicate to customers.<br><br>Develop labels and safety data sheets pursuant to the Global Harmonization System and OSHA's Hazard Communication Standard.<br><br>To promote continuous improvement in the appropriate handling and use of RCF products through employee and customer involvement. | HTIW Coalition member companies will communicate the following types of information to its customers and end-users and will include a summary in the five- year report (and as appropriate in the interim annual reports):<br>• Narrative reports on the most effective control measures and work-practices identified.<br>• Document customer work practice changes using questionnaires, personal visits, or other methods.<br>• Document number of individuals or companies requesting on-site training, monitoring, or other assistance.<br>• Track number of hits on PSP 2017 on HTIW Coalition's web site (ongoing). | • See ***Customer Service Activities*** section. No published reports for 2021.<br>• No news for 2021. See ***Customer Service Activities*** section.<br>• HTIW Coalition member companies received 30 telephone inquiries in 2021. As reported in earlier reports, HTIW Coalition member companies discontinued mailing printed literature in 2013. The information that had previously been mailed (including handling guidelines, reports, multimedia presentations, and related material) is now more readily available from the member company and HTIW Coalition websites. See section titled ***Customer Service Activities*** in the text for more information.<br>• A technical problem with the coding on the HTIW Coalition website prevents reporting on the number of visitors and page views. See the section titled ***Website Utilization*** for more information. |

**Note:** Tasks taken from the PSP 2017 program documents.

**TABLE S-2 (cont'd.).** *PSP 2017 Fifth Year achievements.*

| ***Goal(s)*** | ***Tasks*** | ***Fifth Year Achievements*** |
|---|---|---|
| | ***Customer Service Activities (continued):*** | |
| | • Track number of incoming inquiries to HTIW Coalition and company health and safety information numbers (ongoing).<br><br>• Other customer service activities include:<br>- HTIW Coalition has identified respirator manufacturers and distributors that provide free respirator fit testing and training.<br>- A list of these distributors and manufacturers, grouped geographically, will be made available to customers (ongoing). | • As with the printed materials listed above, member companies are moving away from older methods of delivering information and relying instead on the internet to provide information. Hotline calls have decreased substantially with the availability of online information. In 2021, only 30 hotline calls were received by HTIW Coalition members.<br><br>• See literature published on www.HTIWCoalition.org and discussion in section titled ***Customer Service Activities.***<br><br>• Due to the complexity and widespread availability of respirator distributors and manufacturers, a geographically grouped list of distributors and manufacturers is not practical. Instead, HTIW Coalition published toll free numbers for major distributors and manufacturers and suggestions on how to find help locally. |

**Note:** Tasks taken from the PSP 2017 program documents.

# *PSP 2017: A voluntary product stewardship program (PSP) For Refractory Ceramic Fibers Fifth Annual Report*

## Key Features of PSP 2017

PSP 2017 is posted on the HTIW Coalition website (http://www.htiwcoalition.org/documents/PSP%202017.pdf). This section provides relevant information on each of the key sections. The PSP documentation has been updated each time the industry and OSHA agreed to continue the PSP program. For example, revisions to the PSP 2017 document were made to clarify compliance principles with respect to exceedances of the REG measured by OSHA during site inspections. Important points include:

- Compliance with all applicable OSHA regulations is required (e.g., respirators),
- Confidence intervals based on monitoring data should be considered when evaluating exceedances of the REG, and
- The REG is not the same as an OSHA PEL, and cannot be enforced as such

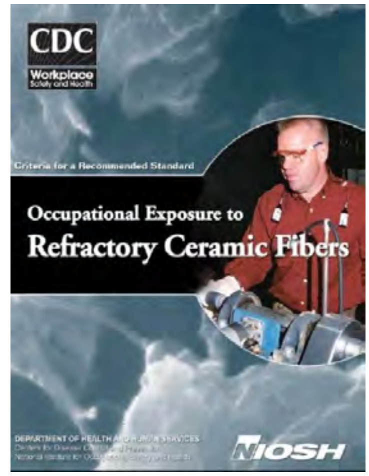
Details are discussed in the "compliance principles" section.

## Scope

PSP 2017 applies to the manufacture, fabrication, furnace-lining installation and removal, and other occupational settings where exposure to RCF may occur. HTIW Coalition and member companies are directly responsible for compliance with the voluntary initiatives of PSP 2017 in their own operations. Additionally, the HTIW Coalition and its member companies provide relevant product stewardship and related information to their customers. To help track the success of stewardship efforts, HTIW Coalition member companies conduct exposure monitoring on a statistical sample of customers each year. Customers monitored are given copies of all monitoring results and suggestions to reduce exposure levels. Sample budgets and monitoring results are provided in the Summary of this document.

The HTIW Coalition and member companies also provide information to regulatory and advisory agencies and to the wider scientific community using several media, including this annual report, material posted on the HTIW Coalition website (and through its companion organization in Europe, ECFIA), and articles published in the peer-reviewed literature.

## Recommended Exposure Guideline (REG)




The HTIW Coalition adopted a recommended exposure guideline (REG) of 0.5 fibers per cubic centimeter (0.5 f/cc = 0.5 f/ml) for RCF in October of 1997. (The REG was lowered several times in earlier years as RCF manufacturers developed improved engineering controls and workplace practices.) The REG is based on prudence and the data developed over the years, which indicates that it is technically and economically feasible to attain an 8-hour *time weighted average* (TWA) concentration of 0.5 f/ml for the majority of jobs in various *functional job categories* (FJCs).[18]

The intent of PSP 2017 is to reduce exposures to the lowest feasible level on the principle that "less is better" when it comes to exposure to any potentially toxic material. In a 2006 Criteria Document,[19] NIOSH adopted a *Recommended Exposure Limit* (REL) of 0.5 f/ml, identical to the REG. The Criteria Document also recommended an action level of 0.25 f/ml because reducing exposures to this level substantially reduces the likelihood of any exceedance of the REG/REL. ***As noted in the discussion of monitoring results, the data continue to indicate that the majority of TWA fiber concentrations are well beneath the REG. Indeed, weighted average fiber concentrations are close to the action level recommended by NIOSH.***

In 2015, a statement of compliance principles, including guidance on statistical procedures for compliance determination, was added to the HTIW Coalition PSP documentation.[20] Details are discussed in the Compliance Principles section below.

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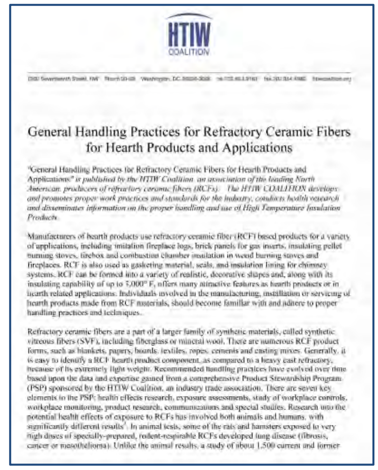
[18] As part of the design effort a statistical sampling plan (specifically a stratified random sampling plan, SRSP) was employed. The universe of jobs was subdivided into eight strata termed functional job categories.

[19] Refer to National Institute for Occupational Safety and Health (NIOSH), 2006. *Criteria for a Recommended Standard, Occupational Exposure to Refractory Ceramic Fibers*. Available online at: http://www.cdc.gov/niosh/docs/2006-123/.

[20] See http://www.htiwcoalition.org/documents/PSP%20Compliance%20Principles.pdf.

## Control Measures and Work Practices



HTIW COALITION

General Handling Practices for Refractory Ceramic Fibers for Hearth Products and Applications

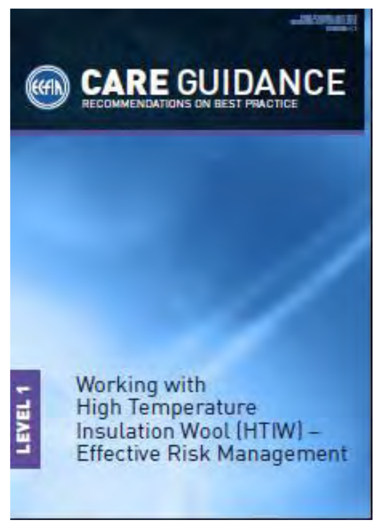
"General Handling Practices for Refractory Ceramic Fibers for Hearth Products and Applications" *is published by the HTIW Coalition, an association of the leading North American producers of refractory ceramic fibers (RCFs). The HTIW COALITION develops and promotes proper work practices and standards for the industry, conducts health research and disseminates information on the proper handling and use of High Temperature Insulation Products.*

Manufacturers of hearth products use refractory ceramic fiber (RCF) based products for a variety of applications, including imitation fireplace logs, brick panels for gas inserts, insulating pellet burning stoves, firebox and combustion chamber insulation in wood burning stoves and fireplaces. RCF is also used as gasketing material, seals, and insulation lining for chimney systems. RCF can be formed into a variety of realistic, decorative shapes and, along with its insulating capability of up to 3,000° F, offers many attractive features as hearth products or in hearth related applications. Individuals involved in the manufacturing, installation or servicing of hearth products made from RCF materials, should become familiar with and adhere to proper handling practices and techniques.

Refractory ceramic fibers are a part of a larger family of synthetic materials, called synthetic vitreous fibers (SVF), including fiberglass or mineral wool. There are numerous RCF product forms, such as blankets, papers, boards, textiles, ropes, cements and casting mixes. Generally, it is easy to identify a RCF hearth product component, as compared to a heavy cast refractory, because of its extremely light weight. Recommended handling practices have evolved over time based upon the data and expertise gained from a comprehensive Product Stewardship Program (PSP) sponsored by the HTIW Coalition, an industry trade association. There are seven key elements to the PSP: health effects research, exposure assessments, study of workplace controls, workplace monitoring, product research, communications and special studies. Research into the potential health effects of exposure to RCFs has involved both animals and humans, with significantly different results[1]. In animal tests, some of the rats and hamsters exposed to very high doses of specially-prepared, rodent-respirable RCFs developed lung disease (fibrosis, cancer or mesothelioma). Unlike the animal results, a study of about 1,500 current and former

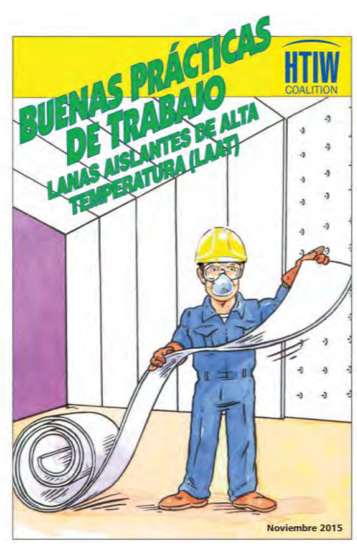
The HTIW Coalition member companies are committed to using product design, engineering controls, work practices, and respiratory protection or a combination thereof to ensure compliance with the REG. As noted in the discussion on monitoring results, ***compliance with the REG is feasible for jobs in most FJCs without the use of respiratory protection***. For certain FJCs, however, including finishing, installation, and removal of after-service insulation, respiratory protection has proven necessary.

The HTIW Coalition and its members attempt to ensure that any changes to product properties do not lead to an increased compliance burden on the part of end-users. There have been no changes in product properties during the past year that would have increased compliance burdens.




## Communications/Outreach

Effective communications are a key element of PSP 2017. This element includes providing relevant information on exposure control techniques, work practices, and respirator use guidelines. The HTIW Coalition website (http://www.htiwcoalition.org), its counterpart in Europe (http://www.ecfia.eu/), and the websites of the member companies contain many useful publications and articles relevant to exposure controls, handling practices, and respiratory protection. The HTIW Coalition website also provides links to other relevant documents, such as the 2006 NIOSH Criteria document for RCF.[21] The ECFIA website provides access to other relevant publications in the peer-reviewed literature (https://www.ecfia.eu/media/).




[21] Online at: http://www.cdc.gov/niosh/docs/2006-123/.

RCF producers provide outreach information using a variety of media and directed to a variety of different audiences (using audience-appropriate language). For example:

- Both the HTIW Coalition[22] and its European counterpart, ECFIA[23] provide handling guidelines for RCF.
- The HTIW Coalition provides a guidance document on obtaining respirators, fit testing, and employee training,[24] and a self-monitoring program for those customers/users who wish to maintain an independent monitoring program.[25]
- Both the HTIW Coalition and ECFIA publish a cartoon booklet, available in several languages[26] for the Spanish language version) that summarizes good work practices for handling RCF.
- HTIW Coalition and ECFIA member companies sponsor articles in peer-reviewed journals on exposure monitoring, employee health monitoring, and results of epidemiological studies (see below). Typically, one or two articles appear annually.

## Relevant articles published in peer-reviewed journals

Pursuant to two elements of the PSP for RCF, health effects research and communication, the HTIW Coalition/ECFIA and their consultants continue to examine and contribute to the peer-reviewed literature on topics related to possible health effects of occupational exposure to RCF. Since the 2016 five-year report, Maxim and Utell published two manuscripts in 2018[27,28] that reviewed RCF toxicity, epidemiology and occupational exposure (see full references in Appendix A). A manuscript updating the ongoing mortality study (summarized below) prepared by the *University of Cincinnati* (UC) researchers has been accepted for publication.[29] Although several articles related to RCF have been published since 2016 and are of interest, none of these contained

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[22] See e.g., http://www.htiwcoalition.org/documents/Gen%20Handling%20Prac%20RCF%20Hearth%20Products.pdf

[23] See e.g., http://www.guidance.ecfia.eu/files/ECFIA-CARE_Guidance-Level_1-Working_with_HTIW-v1_1-2015-09.pdf.

[24] See e.g., http://www.htiwcoalition.org/documents/Guidance%20on%20Obtaining%20Respirators.pdf.

[25] See e.g., http://www.htiwcoalition.org/documents/Self%20Monitoring%20Document%20Combined.pdf.

[26] See e.g., http://www.htiwcoalition.org/documents/Comic%20Book_Spanish_FinalSM.pdf.

[27] Maxim, L. D. and Utell, M. J., (2018). Review of refractory ceramic fiber (RCF) toxicity, epidemiology and occupational exposure. *Inhal. Toxicol.,* 30(2): 1-22.

[28] Utell, M. J. and Maxim, L. D., (2018). Refractory ceramic fibers: Fiber characteristics, potential health effects and clinical observations. *Toxicol. Appl. Pharmacol.,* 361: 113-117.

[29] LeMasters, G. K., *et al*., (in press). Mortality of workers employed in refractory ceramic fiber manufacturing: An update. *J. Appl. Toxicol.* (https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/abs/10.1002/jat.4295)

data or conclusions that would materially change our understanding of the toxicological properties of RCF. Selected articles are included in Appendix A.

***- Research Manuscript Recently Accepted for Publication:***

As anticipated in last year's report to OSHA, UC researchers have updated their ongoing mortality study (as noted above their paper has been accepted for publication and is available online). Earlier epidemiological studies of cohorts occupationally exposed to RCF concluded that the prevalence of respiratory symptoms (LeMasters *et al*., 1998[30]) and interstitial changes (Lockey *et al*., 2002[31]) was similar to that found in other dust exposed populations. Studies also noted a statistically significant association between RCF exposure and pleural plaques (Lockey *et al.,* 2002). In 2017, (LeMasters *et al*., 2017[32]) reported mortality, cancer incidence, and radiographic findings from a 30-year investigation of current and former RCF workers. The mortality study showed no increase in *standardized mortality rates* (SMR) for lung cancer, but urinary cancers were significantly elevated in the higher exposed group (SMR1⁄43.62, 95% CI: 1.33–7.88) and leukemia in the total cohort (SMR1⁄42.51, 95% CI: 1.08–4.94). One death attributed to an alleged mesothelioma (unconfirmed tissue pathology diagnosis) was identified (SMR1⁄42.86, 95% CI: 0.07–15.93) in a worker reporting asbestos exposure. The overall rate of pleural changes was 6.1% while interstitial changes were not elevated.

[30] LeMasters, G. K., *et al.*, (1998). An industry-wide pulmonary study of men and women manufacturing refractory ceramic fibers. *Am. J. Epidemiol*., 148: 910-919.

[31] Lockey, J. E., *et al*., (2002). A longitudinal study of chest radiographic changes of workers in the refractory ceramic fiber industry. *CHEST*, 121: 2044-2051.

[32] LeMasters, G. K., *et al*., (2017). A thirty-year mortality and respiratory morbidity study of Refractory Ceramic Fiber workers. *Inhal. Toxicol*., 29(10): 462-470.

**Results from the latest update:** In their in-press update[33] (now available as an Advance Online Publication), UC researchers indicate:

- This study evaluated the possible association between refractory ceramic fibers (RCF) exposure and all causes of death. Current and former employees (n=1,119) hired from 1952-1999 at manufacturing facilities in New York State and Indiana were included.
- There was no significant association with all causes, all cancers, or lung cancer in any of the three evaluated groups (that is, low exposed <45 fiber-months/cc, high exposed > 45 fiber-months/cc, and total exposed workers).
- In the higher exposed but not the total or lower exposed groups, there was a significant elevation in both malignancies of the "urinary organs" (SMR=3.59, 95% CI 1.44, 7.40) and "bladder or other urinary site" (SMR=4.04, 95% CI 1.10, 10.36). However, at least six of the nine workers with urinary cancers were known smokers and several had occupational exposures to chemical carcinogens such as in dye and metal industries.
- In the lower but not the higher exposed group, there was a significant elevation in malignancies of the lymphatic and hematopoietic system and leukemia. However, there was no consistent leukemia cell type as well as no dose-response relationship.
- There was one pathologically unconfirmed mesothelioma death previously reported in 2017. A second employee currently living with a pathologically confirmed mesothelioma was identified, but the SMR was non-significant when both were included in the analyses. The association of these two mesothelioma cases with RCF exposure alone is unclear because of past significant asbestos exposure.

**Conclusions:** The UC investigators concluded that the study did not demonstrate any increased lung cancer mortality in comparison to local, state, or national populations. They considered the cause for the elevated mortality in urinary cancers as likely multi-factorial including past smoking and potential past industrial exposures during the early years of RCF production. Because of the inability to discern the independent effect of RCF exposure in the presence of past asbestos exposure in both mesothelioma cases and a

[33] See reference in footnote 29 above.

possible association between the RCF production process and urinary cancers, the mortality study is ongoing and deaths from all causes will be monitored.

## Medical monitoring/health effects research

HTIW Coalition member companies continue medical surveillance programs for RCF-exposed employees. The primary purpose of these programs (consisting of X-ray and pulmonary function tests) is to inform employees of any possible health issues that need to be addressed by their physicians. The results of company medical monitoring are provided as needed for the ongoing UC mortality study.

## Web Utilization Statistics

In earlier reports (e.g., the fifth-year report prepared in 2017 after the end of PSP 2012), the HTIW Coalition provided information on the number of visits to the Coalition web page (www.HTIWCoalition.org) and the number of web page views. Similar information is unavailable this year because it was discovered in February 2022 that the Google Analytics code was no longer embedded in the web page code of the Coalition web site.[34] Without this code it is impossible to generate the numbers of visitors to the web page, the number of page views and other statistics previously reported. The appropriate Google Analytics code will be added to the Coalition's web pages so that these statistics will be available for future reports.

Earlier statistics on website visits are instructive. The number of total site users (both new and returning) visiting the HTIWCoalition.org site during 2016[35] was 911, and there were 1,349 pages viewed during these visits. In 2015, the HTIW website received 3,141 visitors who viewed a total of 7,208 pages. These figures show substantial year-to-year variability, which probably continued throughout PSP 2017. When available, web utilization statistics will be included in future reports.

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[34] The Google Analytics code was likely removed inadvertently during website maintenance or updates.
[35] Annual data calculated from 11/15/2015 to 11/15/2016.

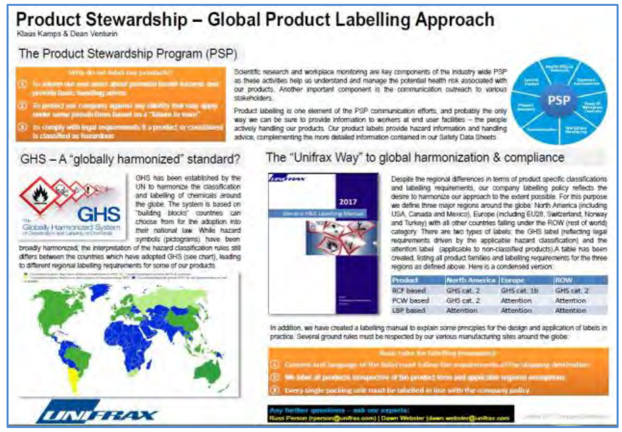
## PSP Outreach Activities and Training Materials

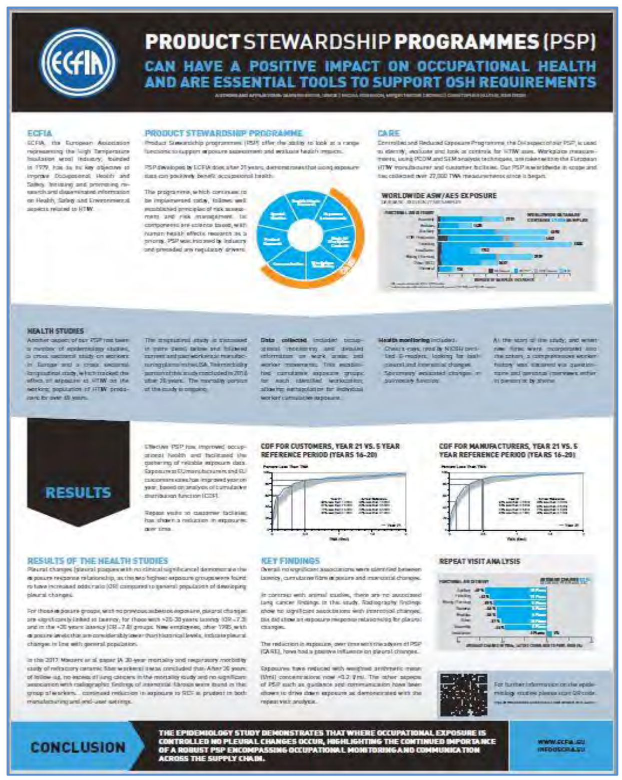
The HTIW Coalition member companies continue to disseminate PSP-related information and materials in a number of forums. Notable recent activities in the US and Europe included:


- In August 2019, Dr. Dean Venturin (Vice President of HTIW Coalition) participated in an OSHA Webinar[36] led by Larry McGowan (Supervisory Industrial Hygienist for OSHA). The Webinar, broadcast live over the internet to OSHA enforcement officers, was designed as an introduction to the HTIW Coalition and to the voluntary PSP 2017 program. A range of topics was covered, including:
    - Introduction to HTIW Coalition
    - HTIW product forms and applications
    - History of cooperative efforts between HTIW Coalition and EPA / OSHA
    - Principles and components of PSP 2017
    - Summary of monitoring results
    - Epidemiology update
    - Enforcement guidance for exposure to RCF.

[36] OSHA Training Institute Webinar #150, Live Event, August 26, 2019

- HTIW Coalition members periodically present PSP-related materials to employees at team events. The example poster pictured here describes the components of PSP and the Alkegen[37] approach to harmonizing product labeling globally. While not always used as part of formal training sessions, poster boards such as this highlight the importance of Product Stewardship, and help to elevate awareness of PSP principles.




***Posters used at internal training sessions and professional conferences***

- In Europe, ECFIA members have presented PSP-related materials at professional conferences. The poster illustrated here was presented by personnel from ECFIA members Morgan Thermal Ceramics, Rath and Unifrax in 2018 at a conference of the British Occupational Hygiene Society (BOHS). This poster summarizes components of the CARE Product Stewardship Programme, global monitoring activities, and recent results of monitoring in Europe.

[37] The training materials pictured were prepared prior to the time Unifrax became Alkegen, and therefore include the former company name.

- ECFIA members have posted *PIMEX* videos on the ECFIA webpage (PIMEX is an acronym for *Picture Mix Exposure*). The PIMEX process involves capturing video of a worker being monitored that, when played back, displays exposure levels concurrently with video of the worker performing various tasks. PIMEX videos help to pinpoint specific processes in need of engineering controls improvements, and work practices that are associated with elevated fiber counts. Precise identification of the causes of elevated exposures allows plants to focus corrective actions, and maximizes the effectiveness of resources dedicated to fiber reductions. The examples posted on the ECFIA webpage[38] illustrate elevated exposures associated with *poor* handling practice, compared to lower exposures associated with *good* handling practices. In North America, HTIW Coalition members have begun using PIMEX videos in recent years.

- HTIW Coalition, ECFIA and individual members sponsor training sessions for Industrial Hygienists (in particular for new hires, but also as refreshers for experienced workers) covering a range of topics including the history and importance of the Product Stewardship Program, detailed procedures for collecting workplace samples and completing the data form, and other issues that emerge related to data collection. These training sessions help to maintain the quality of the data as new Industrial Hygienists are brought into the program. These training sessions continued in 2020 and 2021 via videoconference.

- Both HTIW Coalition and ECFIA maintain websites where the public can view and download PSP-related materials and scientific papers.

***-HTIW Coalition Training Statistics***

[38] See https://www.ecfia.eu/support-care-guidance-videos/

HTIW Coalition member companies provided training sessions upon request and also conducted these during customer monitoring and consulting visits. Manufacturing employees were also provided with training sessions. During 2021, there was a reported total of:

- 11 formal training sessions to train 83 people at customer facilities,[39] and;
- 319 training sessions to train 3,058 people at domestic manufacturing facilities.

***Overall, there were 330 training sessions in 2021 and 3,141 people were trained—the largest annual total to date***. The number of training sessions conducted at customer facilities in 2021 is low compared to years prior to 2020, primarily because of COVID-related restrictions that limited the number of customer visits in both 2020 and 2021. Data for the annual total number of sessions and people trained over the last 5 years of PSP 2017 are shown in Table 1 below. While annual numbers vary, the annual number of sessions and numbers of people trained have increased significantly over the past few years. For the years from 2017 through 2021, there have been 841 training sessions and 9,402 people have been trained to increase worker safety when producing or handling RCF and RCF-containing materials.

HTIW Coalition members continue to support their workers and end users with the training needed to use RCF products safely. An update on the status of PSP literature and video distribution statistics are presented in the Customer Service Activities section of this report.

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[39] "Training" also takes place in less structured ways not counted in the above tabulation. For example, a facility visit typically includes a "walk around" by IHs, actual monitoring, debriefing, and submittal of a written report to company management. IHs from HTIW Coalition member companies estimate that informal training takes place during 80% to 90% of the visits, often including more workers than actually monitored. The above estimates count only those workers that attended more formal training sessions. Estimates for attendance at less formal training would include many more workers.

**TABLE 1.** *Review of training statistics under PSP 2017.*

| Year | Number of Training Sessions | People Trained |
|---|---|---|
| **2017** | 140 | 1,409 |
| **2018** | 122 | 1,393 |
| **2019** | 90 | 1,351 |
| **2020** | 159 | 2,108 |
| **2021** | 330 | 3,141 |
| **Total** | **841** | **9,402** |

## Respirator Use

The PSP 2017 document includes guidance to clarify which respirator should be worn by workers using RCF performing various specific tasks. The PSP 2017 document makes the following general statement on respirator use:

> "The HTIW Coalition and its member companies support OSHA's respiratory protection standards [29 CFR 1910.134 and 29 CFR 1926.103] that form the basis for the HTIW Coalition's respiratory protection program. Training programs and materials will incorporate all relevant requirements of OSHA's respiratory protection standard. The HTIW Coalition member companies will utilize appropriate respiratory protection when employee exposures are not "reliably" below the industry guidelines contained herein (based upon task-specific information; preferably employer-specific data, but relevant data from other sources may also be used). The HTIW Coalition member companies will recommend the use of appropriate respiratory protection to end-users, in the circumstances where occupational exposures may exceed industry guidelines and effective engineering controls are not readily available."

In addition, to ensure that PSP 2017 was specific enough regarding the *assigned protection factor* (APF) of respirators recommended for wear while working with RCF, Everest Consulting

Associates prepared a memorandum to explain why N95 filtering facepiece respirators are appropriate for workers exposed to RCF.[40] The latest guidance reads as follows:[41]

> "When engineering and/or administrative controls are insufficient to maintain workplace concentrations below the 0.5 f/cc REG or a regulatory OEL, the use of appropriate respiratory protection, pursuant to the requirements of OSHA Standards 29 CFR 1910.134 and 29 CFR 1926.103, is recommended. A NIOSH certified respirator with a filter efficiency of at least 95% should be used. The 95% filter efficiency recommendation is based on NIOSH respirator selection logic sequence for exposure to manmade mineral fibers. Pursuant to NIOSH recommendations, N-95 respirators are appropriate for exposures up to 10 times the NIOSH Recommended Exposure Limit (REL). With respect to RCF, both the NIOSH REL and the industry REG have been set at 0.5 fibers per cubic centimeter of air ($f/cm^3$). Accordingly, N-95 would provide the necessary protection for exposures up to 5 $f/cm^3$. Further, the Respirator Selection Guide published by 3M Corporation, the primary respirator manufacturer, specifically recommends use of N-95 respirators for RCF exposures. In cases where exposures are known to be above 5.0 $f/cm^3$, 8 hour TWA, a filter efficiency of 100% should be used. Other factors to consider are the NIOSH filter series N, R or P -- (N) Not resistant to oil, (R) Resistant to oil and (P) oil Proof. These recommendations are not designed to limit informed choices, provided that respiratory protection decisions comply with 29 CFR 1910.134."

## Exposure Monitoring

Another key element of PSP 2017 is an ongoing exposure monitoring effort. This effort—originally implemented on an industry-wide basis in 1990—collects TWA personal monitoring samples from workers in plants operated by HTIW Coalition producers (referred to as "internal" samples) and at customer (and end-user) facilities (referred to as "external" samples). These internal and external samples (see Fig. 1) are collected using a stratified random sampling plan (SRSP) with stated data quality objectives (DQOs).

Data collected as part of this program are used among other purposes to:

- Measure the extent of compliance with the recommended exposure guideline (REG).
- Identify differences in workplace exposures among workers in different functional job categories (FJCs),
- Track time trends in average workplace concentrations,

[40] Available at http://www.htiwcoalition.org/documents/Everest%20Memo.pdf.
[41] Guidance found in Coalition members' Safety Data Sheets under "Respiratory Protection."

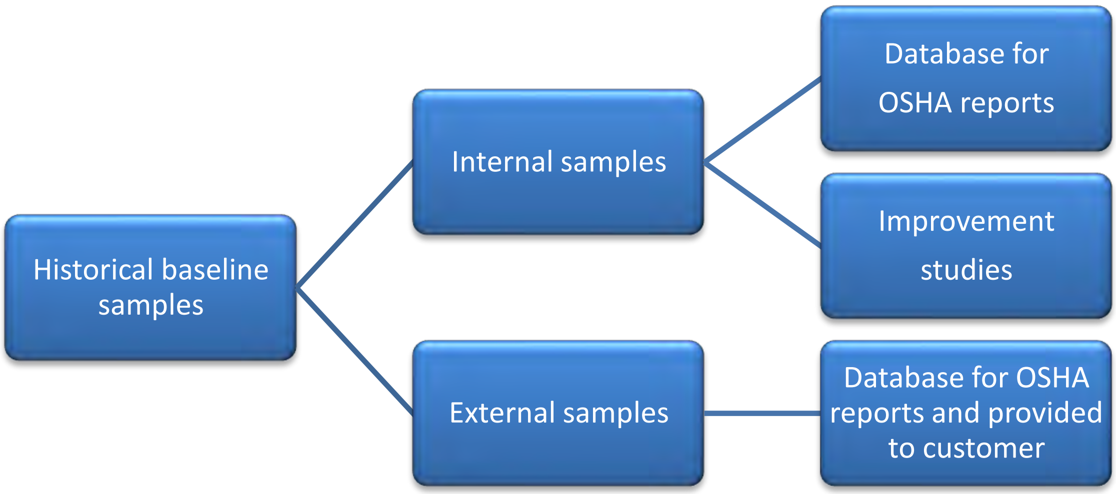


**FIG. 1**. *Data for historical baseline samples.*

- Learn if there are systematic differences between exposures of workers employed in identical FJCs by RCF producers compared to those employed by customers,
- Develop "before and after" snapshots to examine the effectiveness of intervention and monitoring visits, and to
- Investigate whether or not there are systematic differences among customers in different industrial sectors.

Because one major purpose of these samples is to track exposure changes over time, these (both internal and external) are referred to as historical baseline samples (HBS). In addition to historical baseline samples, HTIW Coalition members collect another type of sample in both their own plants and at customer facilities. These samples, called special emphasis samples (SES) are typically used to evaluate the effects of changes in engineering controls or workplace practices (see Fig. 2).

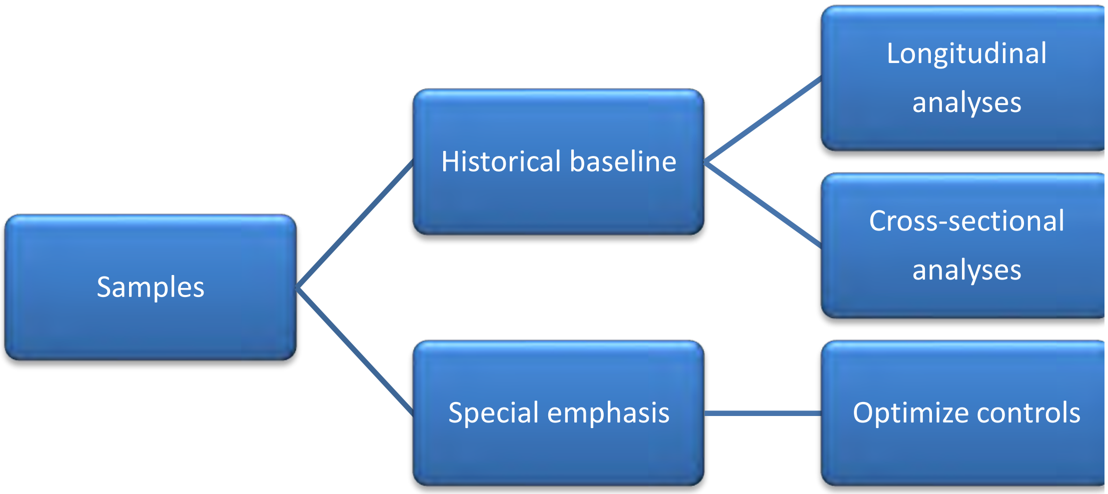


**FIG. 2.** *Historical baseline and special emphasis samples collected as part of the PSP.*

Because SES are not collected using the same protocol as that used for historical baseline samples—for example, workers might not be selected at random but purposively selected as part of a study to evaluate changes in engineering controls or work practices—the results of SES are not comingled with the historical baseline samples. Nonetheless, analyses of SES data can be quite useful in evaluating and improving controls and altered workplace practices. SES are not discussed further in this report—but the lessons learned from the study of SES are incorporated into altered practices which should ultimately be evident in the HBS time series.

### *-Historical Baseline Samples*

For 2021, the exposure monitoring targets for the SRSP were 300 internal samples and 250 external samples. The results of the exposure monitoring effort are discussed in a later section. In terms of accomplishment of the specific collection goals:

- For historical baseline monitoring, 339 internal samples and 86 external samples were collected in 2021. The number of samples collected exceeds the specific numerical target for internal facilities; the target for customer samples was not achieved as a result of COVID-related restriction described above. The distribution of these samples among FJCs is reviewed below.

The percentages of the collection targets reached in 2021 were 113%, 34%, and 77% for the internal, external and total collection budgets respectively.

For the historical baseline samples (both external and internal), separate targets were established for workers in each FJC. These disaggregated sampling targets, termed subgoals, were designed to increase the efficiency of the sampling plan[42] and were not specified in the PSP 2017

**TABLE 2.** *Planned versus actual collection activity in 2021.*

| **Type: External Historical Baseline** | | | |
|---|---|---|---|
| **FJC** | **SRSP Goal** | **Actual** | **Percent Goal** |
| Assembly | 38 | 25 | 66% |
| Auxiliary | 50 | 14 | 28% |
| Finishing | 46 | 30 | 65% |
| Installation | 36 | 8 | 22% |
| Mixing / forming | 21 | 9 | 43% |
| Modules | 14 | 0 | 0% |
| Other (NEC) | 10 | 0 | 0% |
| Removal | 35 | 0 | 0% |
| **Subtotal** | 250 | 86 | 34.0% |

| **Type: Internal Historical Baseline** | | | |
|---|---|---|---|
| **FJC** | **SRSP Goal** | **Actual** | **Percent Goal** |
| Assembly | 11 | 11 | 100% |
| Auxiliary | 50 | 67 | 134% |
| Fiber production | 82 | 102 | 124% |
| Finishing | 41 | 37 | 90% |
| Mixing / forming | 65 | 67 | 103% |
| Modules | 11 | 17 | 155% |
| Other (NEC) | 40 | 38 | 95% |
| **Subtotal** | 300 | 339 | 113% |

[42] The measures of efficiency selected for optimization were the standard errors of the weighted average fiber concentrations in manufacturing and customer locations. The design was based on a Neyman allocation, modified in the light of practical considerations.

document. Table 2 shows the breakdown of the sampling effort among FJCs. As can be seen for ***internal samples*** (i.e., samples from the RCF manufacturing cohort) *subgoal targets were achieved in all FJCs except the finishing and other (NEC) categories.* The FJC targets are established for each company on a pro-rata basis and each company can control the extent of sampling in their respective facilities, under normal conditions. As noted earlier, COVID-19 restrictions resulted in reduced demand for RCF and consequently lower manning at internal plants. Fewer workers were available for monitoring in some FJCs, resulting in the shortfalls noted above.

Collection of customer samples was challenging in 2021 because of COVID-19 restrictions (e.g., travel restrictions, quarantine requirements and social distancing), resulting in only 34% achievement of the customer sample collection target. Note that no samples could be collected in the modules, other (NEC) and removal categories. HTIW Coalition anticipates improved sample collection going forward as COVID-related restrictions are lifted.

It is important to note that any overage or shortfall in achieving subgoal targets does not bias any of the estimates, because the average fiber concentration in each FJC is weighted by the estimated fraction of workers in that FJC rather than the number of samples collected in each category. Shortfalls decrease the efficiency of the sampling plan and inflate standard errors of various estimates. Overages offset the effects of shortfalls and increase the precision of the FJC and weighted averages. However, in cases where no samples could be collected in a category (i.e., in the modules, other (NEC) and removal categories for customers) it is necessary to assume an average value in order to calculate the weighted average. *In the weighted averages presented below, the 2021 average value is assumed equal to the average concentration over the past two years for the Modules, Other (NEC) and Removal FJCs at customer facilities.*

## Analysis of HBS Exposure Data

This section of the report presents an analysis of the HBS exposure data collected as part of PSP 2017, with emphasis on the data collected in 2021. The RCF workplace concentration database upon which these analyses are based now contains more than 31,660 TWA concentration measurements (including samples collected as part of a companion program in Europe). (The actual number of sample cassettes collected is significantly greater than this number because one to four or more cassettes may be required to complete a measurement for a given worker on a given shift,[43] and because SES are not included in this total.) These data, collected (primarily) since 1990, represent the largest and most comprehensive data source on workplace exposure to RCF.

***Statistical techniques are used extensively for analysis of data because (as noted above) workplace fiber concentrations are highly variable.*** The *coefficient of variation* (CV, ratio of the standard deviation to the mean) of workplace concentration measurements (even within a given FJC-plant combination) is often 1.0 (100%) or more—particularly at customer facilities. In consequence, changes in average workplace concentrations cannot be detected immediately, but rather, large data sets collected over relatively long periods of time are required in order to reveal changes that have occurred, particularly if the changes are small.

### *-Data Summaries for 2021—CDFs*

This subsection provides a summary of the baseline samples collected during 2021. The first data summary is *a cumulative distribution function* (CDF) of the workplace concentration data. The data are arrayed in ascending order of TWA fiber concentration, and the CDF plots the cumulative percentage of observations that are less than or equal to each particular TWA concentration.

### *-Internal samples*

Figure 3 shows the empirical CDF for samples *collected at RCF manufacturer* plants (internal samples). Two curves are shown, the first (labeled "NO" in Fig. 3) for the TWA as measured without any correction for the protective effect of respirators, and the second (labeled "YES" in Fig. 3) for effective concentrations corrected for respirator use.[44] Among these 339 observations:

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[43] Cassettes are changed whenever an employee changes jobs (i.e., moves to a different FJC) or if the hygienist believes that the filter might become overloaded. Thus, for example, an employee who works throughout the shift in the same FJC with historically low exposure, would be monitored using a single cassette.

[44] The effective concentration is calculated as follows. Let $u_p = 1$ if the $i^{th}$ worker was properly wearing a respirator and 0 otherwise, $APF_i$ be the *assigned protection factor* (APF) for this worker (APF = 1 if no respirator worn), $r_i = 1/APF_i$, and $f_i$ be the measured TWA for the $i^{th}$ worker. Then the effective concentration = $f_i*(1-u_i) + f_i*r_i*u_i$.

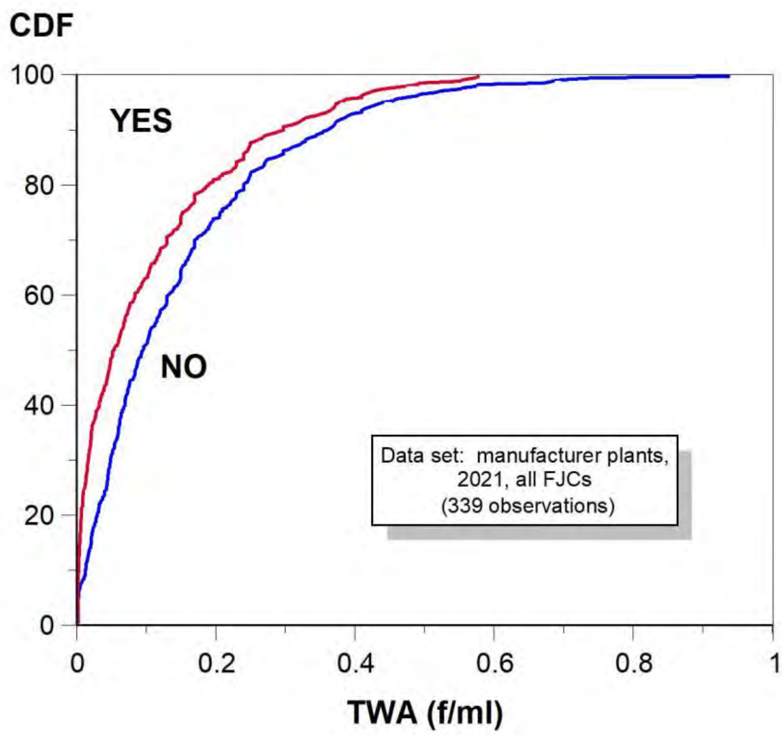


**FIG. 3.** *Empirical CDF of internal monitoring data for 2021 with ("YES") and without ("NO") correction for respirator usage.*

- The overall arithmetic mean and median TWAs (as measured) were approximately 0.15 *fibers per milliliter*[45] (f/ml, ≅ 0.15 *fibers per cubic centimeter* [f/cc]), and 0.10 f/ml, respectively. The standard deviation was approximately 0.15. The aggregate CV was equal to 1.01.
- When adjusted for observed respirator use, the overall arithmetic mean and median TWAs were approximately 0.11 f/ml and 0.05 f/ml, respectively. Thus, respirator use in this population lowered the average workplace concentration by a factor of about 27% (see footnote for an explanation).[46] The standard deviation of the corrected

[45] Note that the *weighted-average fiber concentration* for workers at plants operated by RCF producers in 2016 was approximately 0.12 f/ml. The figure cited above, 0.13 f/ml, is the *unweighted value*, calculated as the average of all observations collected. The weighted value (calculated by multiplying the average value for each FJC by the fraction of workers in each FJC) is a more appropriate benchmark for comparison (in this particular case, the arithmetic mean and weighted average are similar, but this is not true in most years).

[46] While the *assigned protection factor* (APF) for a respirator is 10 or more, the use of respirators reduced the average fiber concentration by only 31% because not everyone wears a respirator. The 31% reduction reflects the proportion of workers wearing respirators as well as the APF of each respirator worn.

workplace concentrations was approximately 0.12, and the aggregate CV = 1.18 for the respirator-corrected data. (Respirators are required to be worn for those jobs where the probable fiber concentration is likely to exceed the REG. Respirators are also provided to any worker who voluntarily elects to use a respirator, regardless of the expected fiber concentration.) *Many workers wore face coverings or masks to comply with COVID-19 requirements in 2021; for these samples, we note that the worker wore a face mask, but no reduction in exposure was assumed (APF = 1).*

- Among plants operated by RCF producers 97% of the TWAs collected were beneath the 0.5 f/ml REG as measured; 99% of the workers were exposed to 0.5 f/ml or less when the protective effects of respirators are included.[47] In 2020, these percentages were 98% and 100% respectively.

***Based upon the CDF curves, exposures at manufacturing plants in 2021 were similar to those measured in 2020.***

Coalition members implemented several physical plant upgrades and/or administrative programs to reverse an apparent uptick in exposures that was observed in 2014. For example, Morgan Thermal Ceramics implemented major local engineering control improvements at two manufacturing facilities in the form of new or additional dust collectors at fiber handling stations, several new booth-style dust filtration systems, improved ductwork and new exhaust hoods at fiber cutting stations, and a new water jet cutter. Alkegen (then Unifrax) developed a "green-amber-red (GAR)" action plan to provide rapid feedback of elevated fiber concentrations to senior management to spur the search for assignable causes and possible corrective actions. These programs were in effect throughout PSP 2017.

The percentage of manufacturer workers with as-measured exposures beneath the REG varies slightly from year to year, and typically falls in within the range of 90% to 98%.

Long time periods and large data sets are required to reliably detect small changes such as those observed between 2020 and 2021. As stated earlier, these monitoring data are highly variable

[47] These percentages, with or without correction for respirator usage, refer to measurements on the day that the worker was monitored. *These numbers should not be confused with the percentage of workers that experience average concentrations in excess of the REG (i.e., chronic overexposure).* On a day-to-day basis the actual workplace concentration experienced by each worker varies in accord with some probability distribution. Each concentration measured is a sample from this distribution.

(the CV is approximately equal to 1.01 in 2021 for manufacturing plants). ***Year-to-year changes are shown as points of interest, but it should be noted that changes must be expected as a result of sample-to-sample variability.*** An aggregated statistic is used (the *weighted average*) to track time trends over the life of the product stewardship program (1990 to 2021) in a subsequent section.

### *-External samples*

Figure 4 shows the empirical CDF for samples *collected at customer facilities* (external samples). Two curves are shown, the first for the TWA as measured without (labeled "NO" in Fig. 4) any correction for the protective effect of respirators, and the second (labeled "YES" in Fig. 4) for effective concentrations. Among these 86 observations:

- The overall arithmetic mean and median TWAs (as measured) were approximately 0.09 f/ml and 0.04 f/ml, respectively. The standard deviation was approximately 0.1. The aggregate CV was equal to 1.18.
- When adjusted for observed respirator use, the overall arithmetic mean and median TWAs were approximately 0.08 f/ml and 0.03 f/ml, respectively. Thus, respirator usage in this population lowered the average effective workplace concentration by a factor of 11%. The standard deviation of the corrected workplace concentrations was approximately 0.11 and the CV was equal to 1.42.
- All (100%) of the TWAs collected at customer facilities were beneath the 0.5 f/ml REG as measured, and as adjusted for respirator use on the day monitored.

***Comparing these data to customer CDF data for 2019 and 2020 indicates that current exposures are lower than those recorded in 2019 and 2020.*** In both 2019 and 2020, approximately 92% of the TWAs collected at customer facilities were less than or equal to 0.5 f/ml as measured; when adjusted for respirator use, approximately 99% and 92% were less than or equal to 0.5 f/ml in 2019

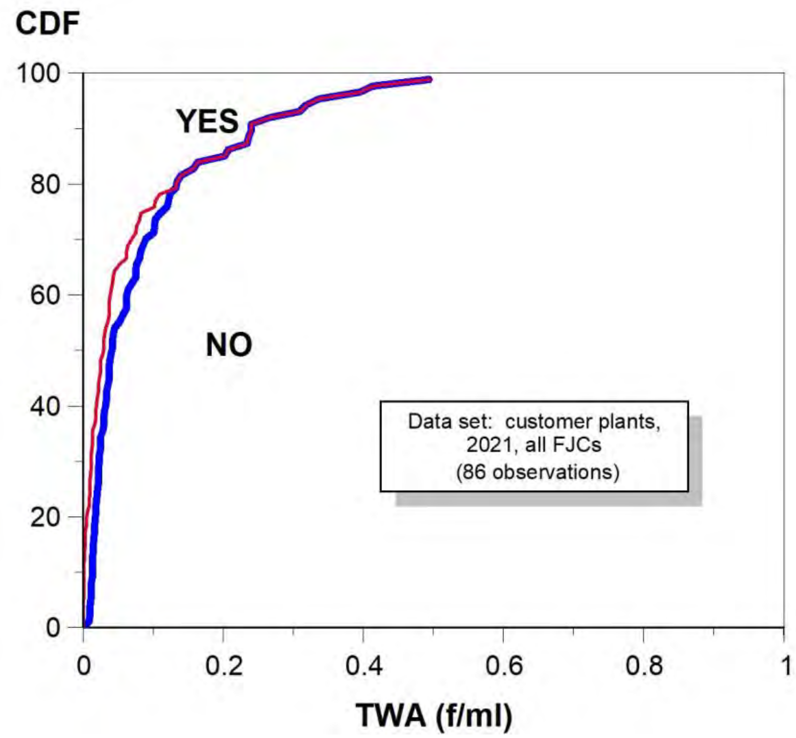


**FIG. 4.** *Empirical CDF of customer monitoring data for 2021 with ("YES") and without ("NO") correction for respirator usage.*

and 2020 respectively. As with samples collected at manufacturing plants, year-to-year changes can be misleading—the customer data are particularly subject to variability, depending upon the type of removal operations that are available for monitoring in any particular year. As noted above, analyses using larger baseline data sets and longer-term time trends provide a better indication of the trends among customer data.

The sampling budgets used for PSP 2017 segregate the worker populations into eight FJCs. There are significant differences in terms of average fiber concentrations (and standard errors) among the FJCs for customers and manufacturers. Using the statistical sampling plan the numbers of samples to be collected in each FJC are chosen so as to minimize the coefficient of variation of the weighted average concentration. These sampling plans are thus optimized in terms of efficiency for a given total sample size, but the number of samples collected in each FJC is *not* solely proportional to the number of workers in that FJC. Therefore, it is necessary to correct for this deliberate over-sampling so that overall CDF curves accurately represent the number *of* *workers* (rather than the *percentages of samples* as shown above) with exposures less than a given TWA value.

Figure 5 shows *weighted* CDF curves for manufacturers and customers in 2021. These curves have been constructed by weighting the empirical CDF curves for each FJC by the fraction of workers in that FJC, and summing across all FJCs. These curves more accurately represent the number of customer and manufacturer workers with exposures (as measured, without adjustment for respirators) beneath a given TWA value. Similarly, Figure 6 shows weighted CDFs for manufacturers and customers with adjustment for respirator use. These curves show:

- Approximately 96% of the workers at RCF manufacturing plants had weighted exposures beneath the 0.5 f/ml REG compared to 99% of the workers at customer plants in 2021.

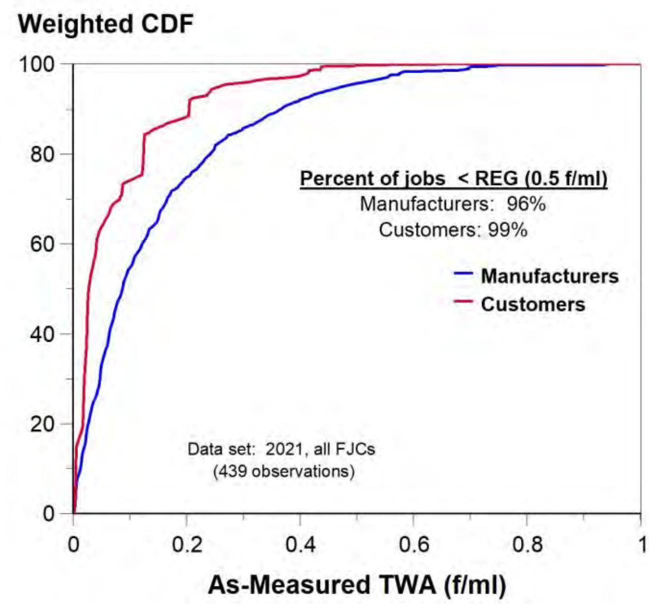


**FIG. 5.** *Weighted CDFs of customer and manufacturer data for 2021 with no adjustment for respirator use.*

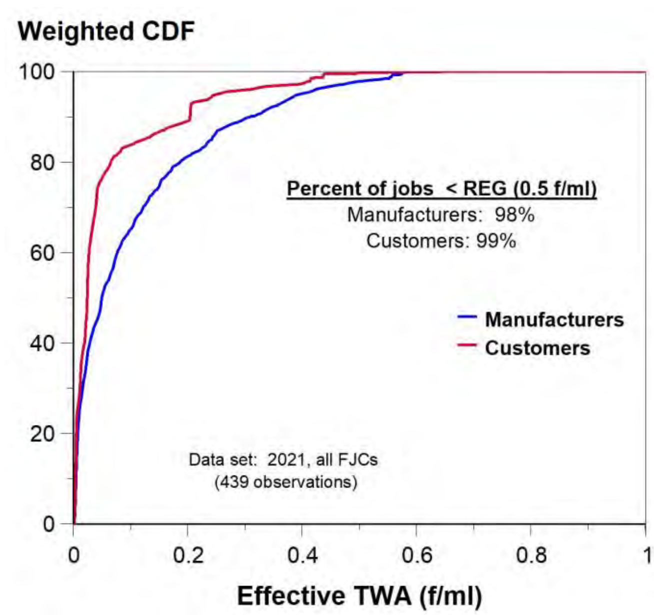


**FIG. 6.** *Weighted CDFs of customer and manufacturer data for 2021, adjusted for respirator use.*

- In terms of the weighted percentage of observations beneath 0.5 f/cc, exposures adjusted for respirator use for customers and manufacturers were similar in 2021. Although these curves indicate that exposures were lower at customer facilities in 2021, it is important to bear in mind that the 2021 customer data set was small, and that several FJCs were not represented.[48] Firm conclusions on differences between customers and manufacturers based on CDF analysis should await a larger customer sample set.

In broad terms, these data indicate that manufacturers and customers alike are able to comply with the 0.5 f/ml REG for a substantial majority—but not all—of the jobs. The next section analyzes workplace concentrations by FJC.

***-Variation by FJC***

The CDFs plotted in Figures 3 through 6 are based on the workplace concentrations as measured, without regard to exposure category (FJC). As such, these distributions reflect the variability within exposure category *and* the distribution of sampling effort among FJCs. Prior analyses of these data have shown that workplace concentrations vary with FJC, plant, specific unit operation/process, and (in the case of customer observations) the industrial end-use sector. This subsection provides data summaries by FJC for both manufacturer (internal) and customer samples. The purpose of these comparisons is to identify exposure differences among FJCs and identify FJCs with relatively high exposure. The average workplace concentration for an FJC is one criterion (the number of exposed workers is another) used for targeting exposure reduction efforts.

Figure 7 presents a bar chart showing the average (arithmetic mean) TWA by FJC (without [dark fill] and with [light fill] adjustments for respirator use denoted RTWA) for *internal samples* (workers employed by RCF producers). The FJCs are arranged in descending order of measured average concentrations (without correction for respirator use) for the year 2021. Shown also (lines

[48] When preparing the weighted CDF curves, it is necessary to have data from all FJCs; for these curves, the most recent available data sets are used to approximate 2021 exposures in the customer FJCs for which data are not available (Modules, Other (NEC) and Removal). Results shown are therefore approximate.

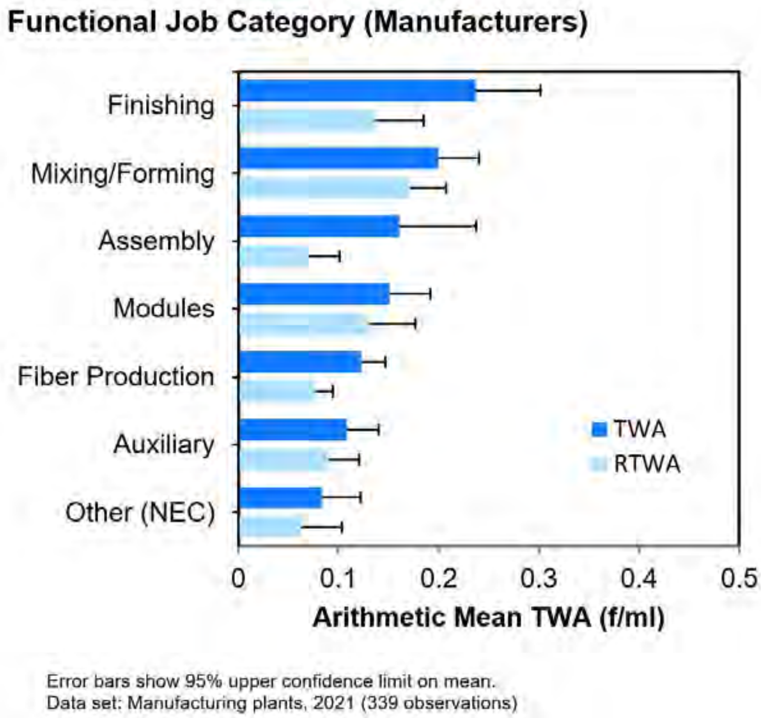


**FIG. 7**. *Arithmetic mean TWA of manufacturer workplace data by FJC as measured, and as corrected for respirator use, 2021*

drawn from each bar) are 95% one-sided upper confidence limits of each mean, which indicate the precision of these averages.

Over the years *analysis of variance* (ANOVA) techniques have consistently shown that the differences among mean workplace concentrations for these FJCs are statistically significant, and this continues to be true for the data collected in 2021. The particular pattern of exposures by FJC varies somewhat from year-to-year as a result of random fluctuation and progress (or occasional setbacks) in exposure reduction efforts. (Comparisons with historical sampling results are shown below.) Data collected in 2021 confirm the broad pattern of results seen in earlier years for most FJCs. For example, exposures in the finishing and mixing/forming FJCs are typically relatively high. In the case of finishing, this is true because mechanical energy is transferred to RCF materials by (for example) saws, sanders or grinders. Exposures can be high in the mixing/forming FJC because of the mixing process—when bulk RCF is added to mixing tanks some RCF may become airborne if proper engineering controls and work practices are not implemented.

Exposures in other FJCs tend to be relatively low. For example, tasks in the auxiliary (e.g., supervision, shipping, maintenance) have historically been associated with relatively low

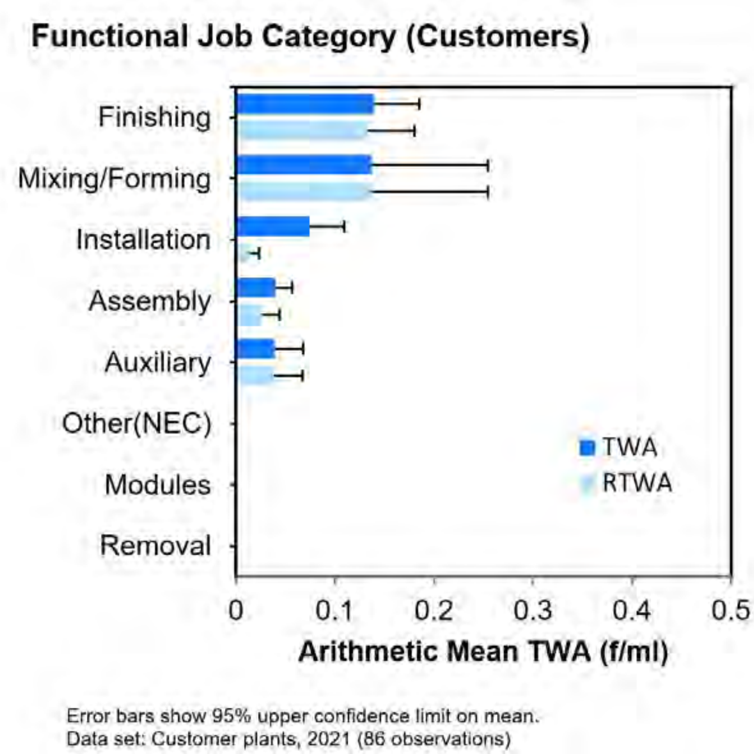


**FIG. 8.** *Arithmetic mean TWA of customer workplace data by FJC as measured, and as corrected for respirator use, 2021.*

concentrations. Figure 7 shows that these relationships held true in 2021. Similarly, exposures in other (NEC) have been low (comparable to the auxiliary category). This remains true in 2021.

Figure 8 shows the same information as Figure 7, but for *customer (external) samples* for the year 2021. *As noted earlier, no customer samples could be collected in several categories in 2021 (modules, other (NEC) and removal)—bars for these FJCs are missing from Figure 8.* FJCs with relatively high measured concentrations include finishing and mixing/forming. The finishing and mixing/forming FJCs have historically had relatively high concentrations. In 2021, the pattern of arithmetic mean concentrations in customer FJCs shown in Figure 8 is similar to that observed in most previous years, for those FJCs that could be monitored in 2021.

It is useful to note that average *effective concentrations* (adjusted for effects of respirators) in all FJCs at customer facilities in 2016 were well beneath the REG of 0.5 f/ml. The highest respirator-adjusted average concentration was approximately 0.14 f/ml in the mixing/forming FJC.

Note also from the averages plotted in Figures 7 and 8 that the ratio of the effective concentrations (corrected for respirator use, the light bars) to measured concentrations (the darker bars) varies with the FJC. This occurs because the extent of respirator use varies with workplace concentration and, therefore, with FJC. Maxim *et al*.[49] developed models, called *respirator response functions* (RRF) that describe the probability that a respirator will be worn as a function of workplace concentration. Because respirator use varies with TWA, workers in FJCs with the highest measured concentrations are not necessarily those with the highest effective exposure. This is true because:

- For FJCs where the typical concentration is relatively low (such as the other (NEC) and auxiliary categories in Fig. 7), respirators are not required and not generally used. (All workers have the option of voluntarily using respirators, and some elect to do so even though concentrations are expected to be relatively low.) For these FJCs the average workplace concentrations corrected for respirator use are nearly the same as those as measured (because few workers elect to wear respirators), but are relatively low in any event.
- For FJCs where the typical concentration is relatively high (such as the installation category in Fig. 7), respirators are required for many jobs. For these FJCs the average workplace concentrations corrected for respirator use are substantially beneath those as measured and, therefore, are also relatively low. Respirators, if worn properly, reduce the effective concentration substantially (by a factor of 10 or more, depending upon the type of respirator).
- Thus, effective exposures are usually highest for those FJCs with measured workplace concentrations in "the middle;" higher than those in the low-exposure FJCs, but not high enough to require respirator use.

Because of this phenomenon, *the rank ordering of FJCs in terms of effective exposure differs from that as measured*. For example, the average as-measured concentration for workers in the finishing FJC was highest among all FJCs at manufacturer facilities in 2021. But, a large

[49] Maxim, L. D., *et al.*, (1998). The development and use of respirator response functions as part of a workplace exposure monitoring program for control of potential respiratory hazards. *Reg. Toxicol. Pharm.*, 27: 131-149.

percentage of the installation workers monitored wore respirators, so the respirator-adjusted concentration is reduced beneath that of mixing/forming workers.

### *-Variation by FJC: Historical Baseline Comparisons (Internal Samples)*

The information presented in Figures 7 and 8 above shows how 2021 average workplace concentrations (internal and external samples) vary with FJC with and without adjustments for respirator use. Analyses presented in this subsection show how the measured 2021 data collected at plants operated by HTIW Coalition members compare with historical norms by FJC. Following the pattern of recent reports, we have defined the baseline period as the five years immediately prior to the current year. The current data are for year 2021, and the baseline period is, therefore, defined as years 2016 through 2020.

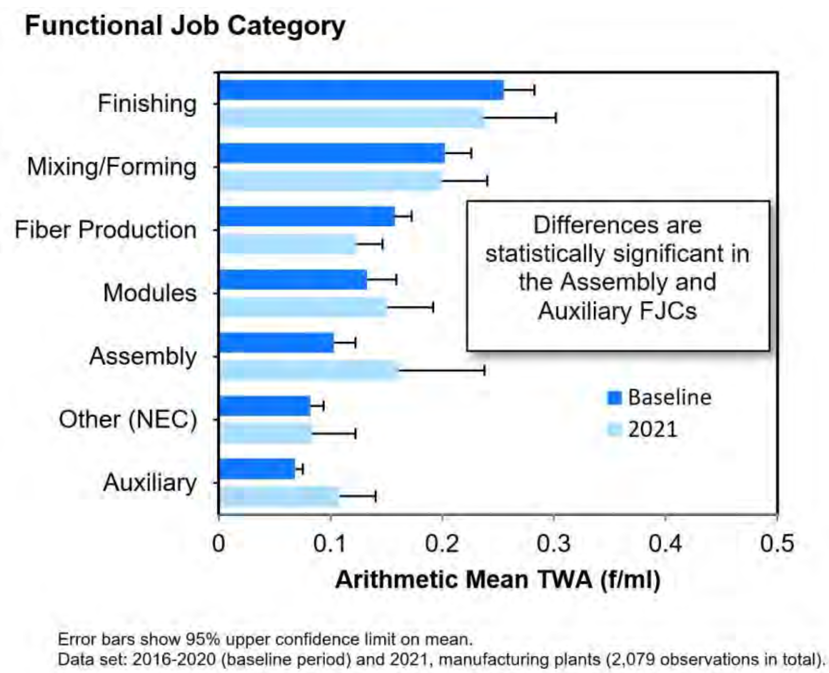


**FIG. 9.** *Arithmetic mean TWA of internal workplace data collected from 2016 to 2020 compared to measurements taken in 2021, by FJC.*

Figure 9 presents a bar chart showing the arithmetic average TWA concentration (as measured) for the five-year baseline period (darker bars) and for the year 2021 (lighter bars) for each FJC for *internal samples*. FJCs are shown in descending order of the (2016 - 2020) five-year average TWA concentration. The one-sided 95% upper confidence limit on the mean is shown as a line extending from each bar. Comparing data for 2021 with the baseline, average concentrations were lower in 2021 for all FJCs except assembly, modules and auxiliary, and the differences were statistically significant for the assembly and auxiliary FJCs categories. (RCF manufacturers do not normally engage in either installation or removal jobs, and these FJCs are not shown in Fig. 9.) Average exposures (and upper 95% confidence limits) are beneath the REG of 0.5 f/ml for each FJC. The HTIW Coalition member companies will continue to monitor these exposures closely and continue to work towards reducing concentrations in all FJCs.

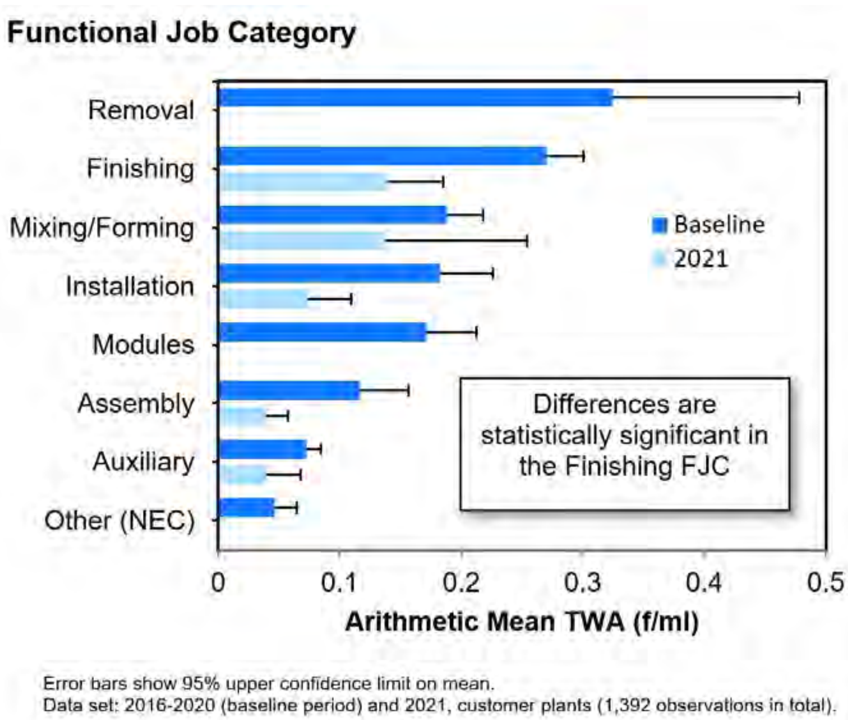


**FIG. 10.** *Arithmetic mean TWA of customer workplace data collected from 2016 to 2020 compared to measurements taken in 2021, by FJC.*

### *-Variation by FJC: Historical Baseline Comparisons (Customer Samples):*

Figure 10 shows average TWA concentrations at customer facilities by FJC for the (2016-2020) five-year baseline period compared to year 2021 data. Compared to the baseline exposure period, average workplace concentrations have declined in all FJCs in 2021 and the difference was statistically significant for the finishing category. Changes in other FJCs vary in magnitude—some are large, others are relatively small, but they fail to reach statistical significance. The baseline data for removal are high this year because of some large values recorded over the baseline period.

Until these larger numbers have time to 'age' out of the baseline set, the baseline levels for the removal FJC will continue to be high.

Although the HTIW Coalition member companies were unable to collect removal samples in 2021 because of COVID-19 restrictions, it is important to recall several facts about exposures in this category. In earlier reports, removal concentrations were found to be low, but the Coalition cautioned that it was premature to claim any breakthrough in this area. We suggested several reasons to withhold judgment:

- Removal samples are difficult to obtain;[50] consequently IHs tend to maximize the number of samples that can be collected at any given customer facility. And, the number of removal observations collected annually is usually relatively small (during the 5-year baseline period, the number of removal samples collected ranged from 5 to 12 samples, with an average yearly total of 8 samples) and beneath the SRSP target of 35 samples. Thus, the yearly average can be greatly influenced by a single removal operation.
- The removal FJC includes a wide variety of activities, from single module "spot" or "maintenance" removals, to removal of kiln car insulation or mold knock-out procedures at foundries, to full-scale removal of insulation from a large industrial furnace. Fiber concentrations vary widely with the type of removal being monitored.
- Experience suggests that it is very difficult to reduce exposures in the removal category by application of typical engineering control methods, except for relatively small-scale removal operation such as mold knock-out and kiln car removals (in these operations RCF is removed from relatively small parts compared to an entire furnace, and it may be possible to apply some form of engineering controls).
- Removals vary with environmental conditions, from small confined spaces to large open (sometimes outdoor) areas. Removals in confined spaces are usually associated with higher fiber concentrations.
- Variations in work practices result in variations in exposures.

[50] The weighting factor for removal is 0.045. That is, approximately 4.5% of the workers are engaged in removal activities, and they occur infrequently.

These factors result in significant variation in exposure from job-to-job and from year-to-year in this FJC. We have observed large swings in yearly averages in the removal category in the past—a brief review of some past levels illustrates this point:

- In 2003 the average removal concentration was 2.5 f/ml;
- In 2004 the average concentration fell to 1.4 f/ml;
- In 2005 the average concentration fell to 0.76 f/ml;
- In 2006, the average increased to 1.7 f/ml;
- In 2007 the average increased again to 2.4 f/ml;
- In 2008 the average concentration fell to 0.67 f/ml;
- In 2009 the average concentration fell beneath the REG to 0.42 f/ml;
- In 2010 the average increased to 0.67 f/ml;
- In 2011 the average fell to 0.44 f/ml;
- In 2012 the average fell to 0.25 f/ml;
- In 2013 the average increased to just over 1.0 f/ml;
- In 2014, the average fell to 0.44 f/ml

Based upon experience and the nature of the removal process, we expect to see continued high variability and elevated concentrations in this category. Experience has shown that year-to-year increases or decreases in average TWA concentrations are not uncommon, given the high variability in these data. Some of the changes shown in Figures 9 and 10 are relatively modest and not statistically significant. Data collected over many years are required to reliably reveal trends among slowly-changing data with such high variability. Other changes are larger, and resulting trends are more quickly revealed. We examine time trends covering data collected from 1990 to 2021 in the next section.

## Longitudinal Time Trends

This section examines trends in weighted-average fiber concentrations among RCF manufacturers and their customers (and end users). Time trends for selected FJCs are also presented.

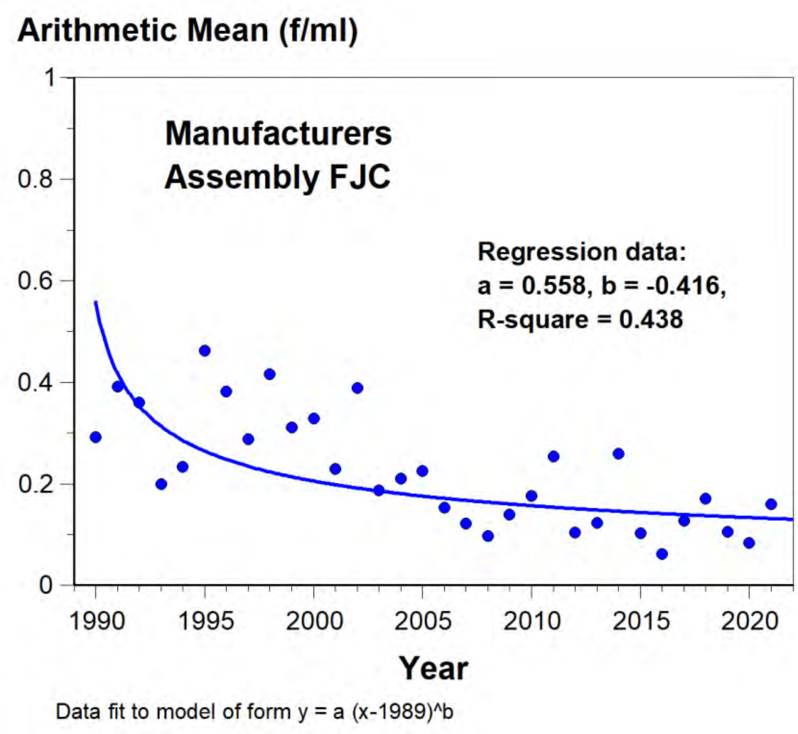


**FIG. 11.** *Average TWA fiber concentration trend in assembly FJC at manufacturing facilities.*

## *-Manufacturer Exposure Trends*

This section examines time trends in several FJCs at RCF manufacturing facilities from 1990 to 2021. Regression models are fitted to the data.

Logically, it is plausible that the reduction in average fiber concentration might be greater for those FJCs that had relatively high fiber concentrations to begin with, as these have generally been the focus of efforts to reduce fiber concentrations.[51]

Figure 11 shows a time trend of average TWA fiber concentrations in the assembly FJC, from 1990 to 2021, at facilities owned/operated by RCF producers. There has been substantial improvement in this category since 1990—as shown by the fitted trend. Actual measurements in the assembly category are consistent with the trend line, with some variability, from 2017 through 2021. Past measurements in the category show that such variations are not without precedent.

[51] This conjecture is supported by data in most FJCs. Removal is an exception, but manufacturers do not engage in this FJC.

Shown also in Figure 11 is a fitted model (solid line). The model is of the form $f_T = \beta_0 (T - 1989)^{\beta 1}$. In this model, $f_T$ is the average fiber concentration in year T, and $\beta_0$ and $\beta_1$ are parameters to be estimated from the data. For these data, the best fit values for the two parameters $\beta_0$ and $\beta_1$ determined by non-linear least squares are 0.558 and –0.416, respectively ($R^2 = 0.438$).

This particular model was suggested by analogy with learning curves (Asher, 1956,[52] U.S. Army Missile Command, 1965[53]) used to describe how the unit cost of procurement of aircraft, missiles, and other weapon systems varies with the cumulative production quantity. Analysis of unit cost data for various types of aircraft (Asher, 1956) indicated that, when the cumulative production doubled, the unit cost decreased to a value 70–90% of the base cost. The "slope" as it was called is numerically equal to $2^{\beta 1}$. For the workplace concentration data in this FJC, the slope is $2^{(-0.416)} = 0.75$, indicating that for each doubling of the time since the baseline time (1989) the average concentration decreases to approximately 75% of its original value.

The learning curve model projects a continuous decrease in fiber concentration, albeit at lower rates. Thus, this model captures diminishing returns.

Concentrations were slightly above the trend line in 2021; in 2019 and 2020 the average values fell beneath the trend line. Such variability is consistent with past results, and is to be expected for these monitoring data.

As a second example, Figure 12 shows a similar time trend for the fiber production FJC at RCF manufacturing plants from 1990 to 2021. Again, we observed substantial improvement over this period. As with the assembly FJC, there is substantial variability, but the model appears to fit the data fairly well. Note that the average TWA in the fiber production FJC decreased slightly in 2021 compared to 2020. For the workplace concentration data in this FJC, the slope is $2^{(-0.325)} = 0.80$, indicating that for each doubling of the time since the baseline time (1989) the average concentration decreases to approximately 80% of its original value.

Other FJCs exhibit greater variability and less dramatic decreases over time. Figure 13 shows the time trend for the finishing FJC at RCF manufacturing facilities from 1990 to 2021. Clearly, the variability in this category is quite high, and while there has been overall progress since 1990 as measured by the regression model, year-to-year results are sometimes deceiving.

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[52] Asher, H., (1956). Cost-Quantity Relationships in the Airframe Industry. Rand Corp., Santa Monica, CA. Report R-291.

[53] Army Missile Command, (1965). Alpha and Omega and the Experience Curve. April 12. pp. 168.

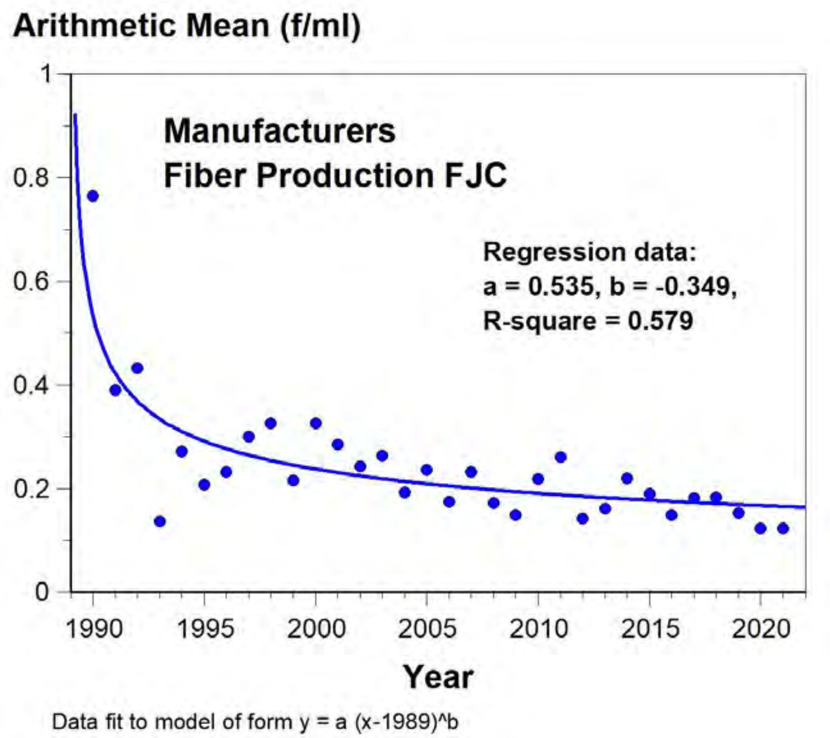



**FIG. 12.** *Average TWA fiber concentration trend in fiber production FJC at manufacturing facilities.*

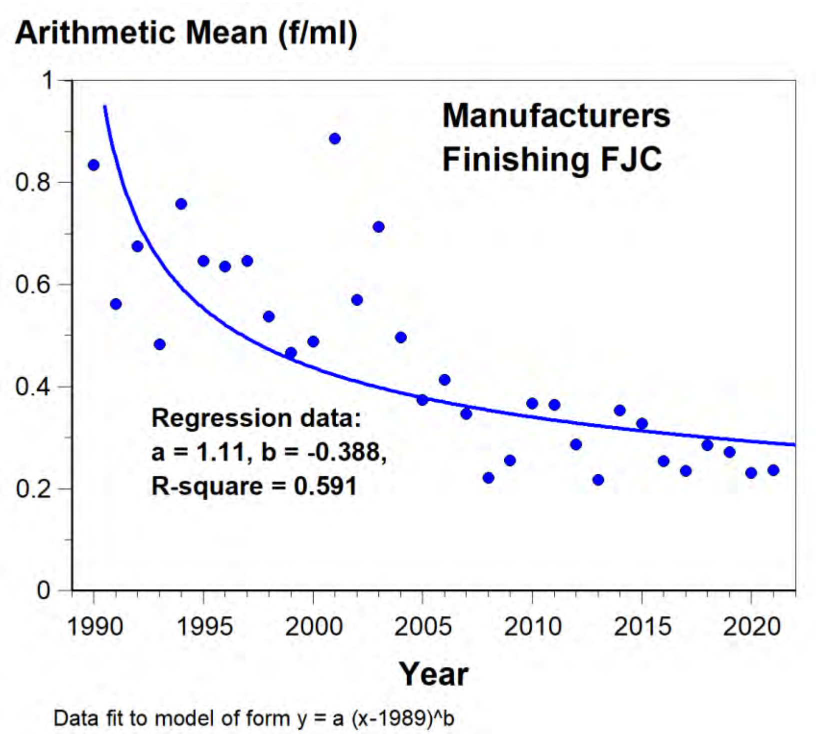



**FIG. 13.** *Average TWA fiber concentration trend in finishing FJC at manufacturing facilities.*

It has been noted in previous reports that, while the HTIW Coalition member companies have expended considerable effort to reduce concentrations in the finishing FJC, it should not be surprising if occasional apparent "setbacks" occur because of the high variability. For example, in 2018, the average concentration (0.285 f/ml) increased compared to 2017. In 2019, the average concentration decreased slightly to 0.27 f/ml, and remained beneath the 2018 value for the remainder of PSP 2017. In 2021 the average concentration increased slightly, but is below the predicted trend line and well below the REG at 0.236 f/ml.

Relatively long time periods will be required to clearly define small changes in the finishing category because of the high variability evident in Figure 13. Since 2001, finishing concentrations have decreased substantially. Overall, the trend (particularly since 2001) is encouraging. In 2021, levels are 73% lower than the high value measured in 2001, and the data exhibit less variability over the past 8 years. The HTIW Coalition member companies remain committed to reduce exposures in this category, but it will take a fairly large number of years to confidently demonstrate small year to year improvements.

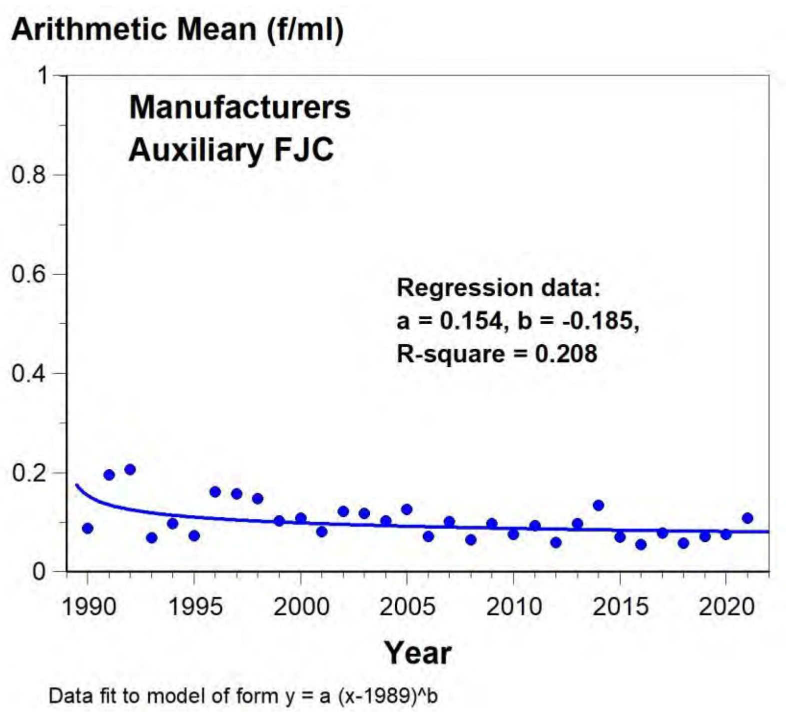



**FIG. 14.** *Average TWA fiber concentration trend in auxiliary FJC at manufacturing facilities.*

Figure 14 shows the much more gradual decline in average TWA concentrations in the auxiliary FJC at RCF manufacturing plants from 1990 to 2021. Because workers in this FJC are generally not directly exposed to RCF but, rather, work near places where RCF is being handled or processed, average TWA concentrations are quite low on average (examples of typical tasks are maintenance, shipping, and packaging) and relatively little effort has been devoted specifically to reductions in this category. The best-fit exponent indicates that fiber concentrations have decreased, but this decrease is non-significant and the trend is accurately described as "flat."

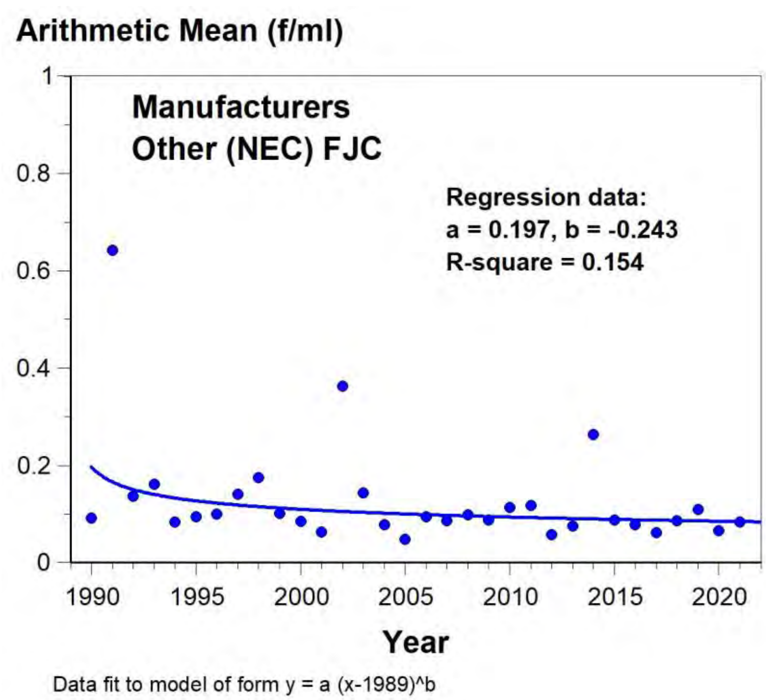



**FIG. 15.** *Average TWA fiber concentration trend in other NEC FJC at manufacturing facilities.*

Figure 15 shows the time trend for the other (NEC) FJC. As can be seen, the average fiber concentrations in this category have been low and relatively flat in past years. However, there was a significant 'uptick' in 2014 to 0.263 f/ml that has been discussed in previous reports. In 2016 the average value was again below the trend line at 0.08 f/ml. Based on actions taken as a result of the 2014 uptick, it is expected that this FJC will continue to exhibit low average concentrations.

Figure 16 shows the time trend in the mixing/forming FJC at RCF manufacturing plants from 1990 to 2021. As with the finishing FJC, we observe fairly high variability, and a relatively flat trend (there is a small downward trend). There was a large increase in this category in 2010. However, the average concentration apparently returned to the trend line in 2011 through 2013 and increased again in 2014. In 2015 and 2016, the average concentration fell to 0.19 f/ml and 0.17 f/ml, respectively, below the expected value based on the trend line.

One of the reasons for high variability in the mixing/forming category is that exposures in the two tasks, mixing and forming, are significantly different—mixing entails higher exposures, even when controls are in place, such as covers on mix tanks and use of local exhaust ventilation. Forming is a wet process, with typically low exposures. Thus, the value measured for a worker on a given day depends upon what tasks the worker is doing on the day monitored. If subsequent years show significantly higher average exposures in this FJC, it may be appropriate to disaggregate this category into two separate categories, mixing and forming, and to establish separate collection subgoals for each.

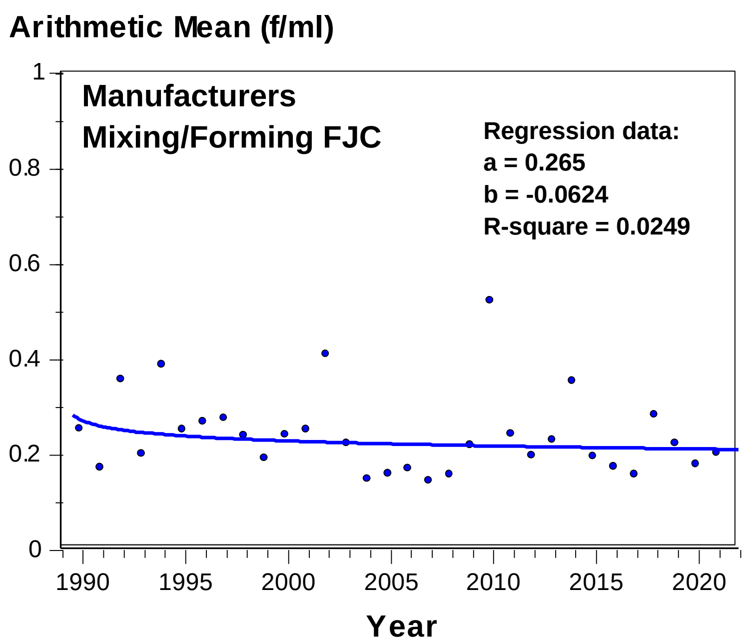



**FIG. 16.** *Average TWA fiber concentration trend in mixing/forming FJC at manufacturing facilities.*

### *-Weighted Average*

Figure 17 shows a time trend of *weighted-average* fiber concentrations from 1990 to 2016 at facilities owned/operated by RCF producers, i.e., the weighted average concentration is given by the formula $\Sigma w_i TWA_i$, where $w_i$ is the weight assigned to the $i^{th}$ FJC and $TWA_i$ is the measured concentration for that FJC. The weights are set equal to the fraction of workers employed by RCF producers (or customers) engaged in each FJC. Thus, the weighted exposure measures the average TWA fiber concentration experienced by the average worker employed at a facility operated by a RCF producer. For manufacturers, the weights are determined annually from an employee census provided to Data-Pro Consultants by each of the plants operated by HTIW Coalition member companies.

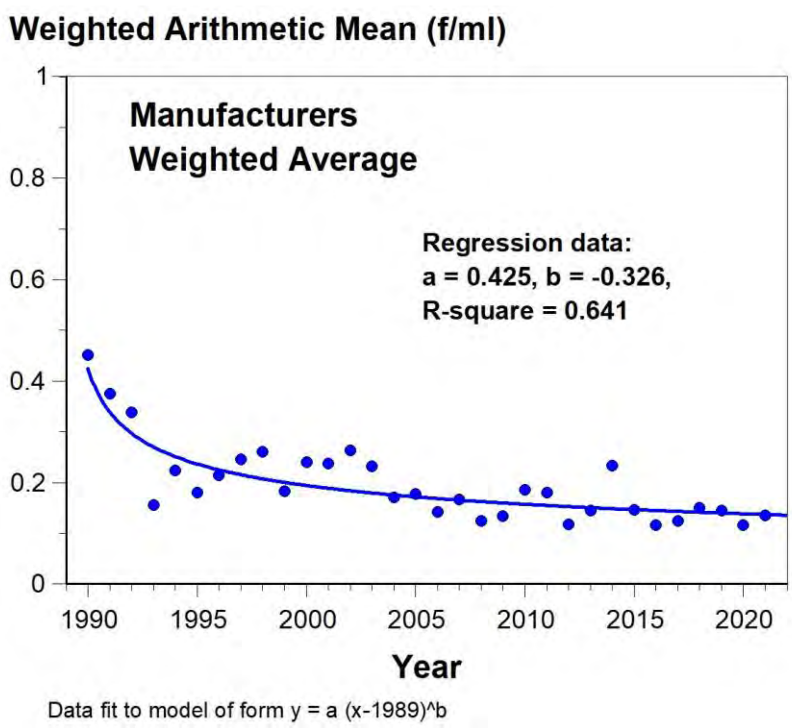



**FIG. 17.** *Time trend in weighted average TWAs at manufacturing facilities.*

The learning curve percentage for the weighted-average exposure in manufacturing facilities is approximately 80%. Numerous time-trend models (e.g., power-law, semi-log, and linear) have been evaluated, and all point to statistically significant decreases over the period 1990–2021.

Note that the weighted-average TWA concentration in 2021 (0.135 f/ml) has increased slightly compared to 2020, but lies very close to the predicted trend line. Figure 18 illustrates the individual FJC contributions to this change, which are largest for the auxiliary, assembly and mixing/forming FJCs. Overall, the increases in are relatively minor; the net effect is a 0.02 f/ml increase shown in Figure 18. The weighted average concentration for 2021 is well beneath the REG of 0.5 f/ml.

In 1990, the weighted-average TWA concentration was approximately 0.45 f/ml; by 2021, exposures decreased to 0.135 f/ml—a 70% reduction. As is true of most FJC trends for RCF manufacturing facilities, the weighted-average regression demonstrates relatively rapid improvement in early years, with gradually decreasing rates of improvement over time.

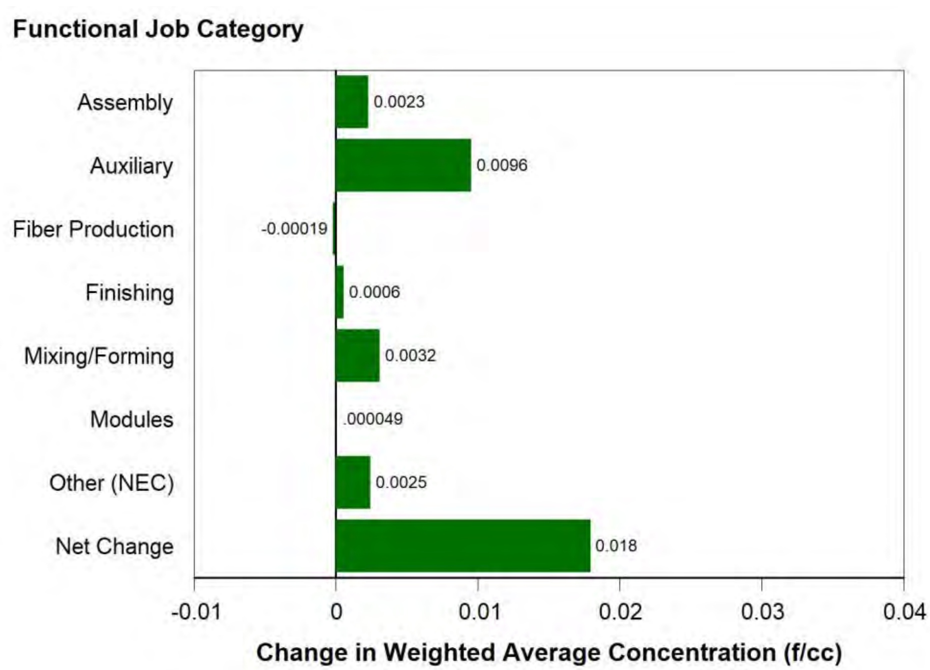



**FIG. 18.** *Components of change in weighted average TWA fiber concentration at manufacturing facilities, 2020-2021.*

### *-Customer Exposure Trends*

What are the exposure trends among the customer population? Figure 19 shows the time trend for the finishing FJC at customer plants. Over the period from 1990 to 2021, the highest average TWA concentration measured in this category was slightly more than 3.0 f/ml in 1991. Since then, the average TWA concentration fell to approximately 0.14 f/ml in 2021, a decrease of 95%. The average TWA concentration (unadjusted for respirator use) in 2021 is beneath the REG for finishing workers. When adjusted for respirator use the average exposure was 0.13 f/ml (see Fig. 8), well beneath the REG.

The regression model shows a downward trend, but at a slower rate in recent years. The learning curve coefficient for this category is 67%. As with other FJC trends we have examined, year-to-year increases have occurred in the finishing FJC, but the overall trend is towards lower average concentrations. Examining average concentrations in recent years we see that there has been significantly less variability over the last 8 years (2014 to 2021) compared to the period 1990 to 2014, and the average levels have shown a steady gradual decline. This result is encouraging, but we caution that it is likely premature to declare victory in this category. Recall that in 2020

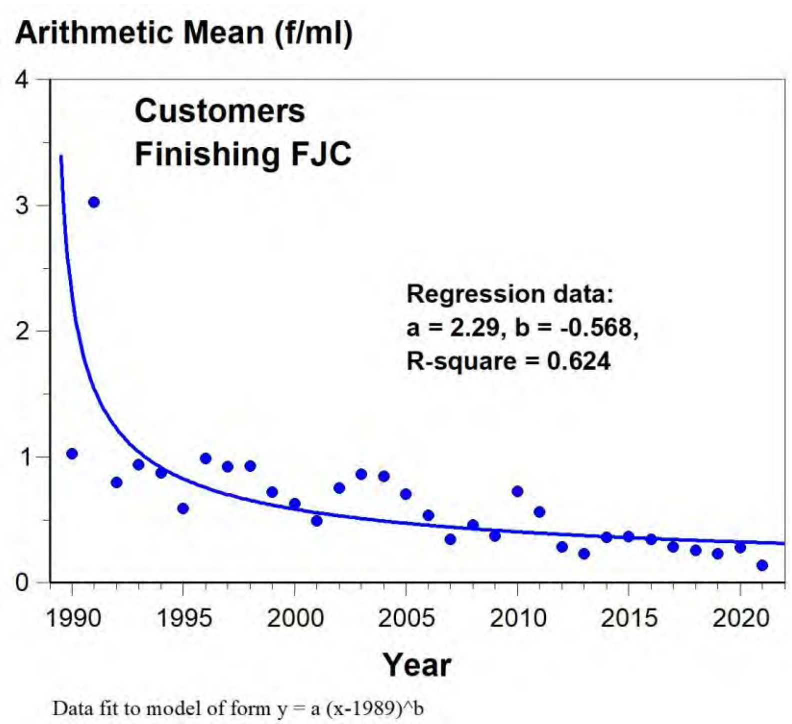



**FIG. 19.** *Average TWA fiber concentration trend in finishing FJC at customer facilities.*

and 2021 relatively few customers were monitored; when increased customer monitoring resumes it would not be surprising if occasional upticks in finishing levels occur. While it is true that substantial progress has been made since 1991, there are still customer facilities with elevated RCF concentrations (as recently as 2010-2011). When such facilities are discovered through monitoring visits, HTIW Coalition member companies work with customer management to reduce elevated exposures. In fact, the HTIW Coalition member companies will continue to encourage all customers to achieve the maximum feasible reductions.

Figure 20 shows the time trend for the installation FJC at customer plants. Here again, we see improvement since 1990—the average TWA fell from 1.61 f/ml in 1990 to 0.07 f/ml in 2021, a decrease of approximately 96%. Note that concentrations in this category have decreased substantially from high (and probably unrepresentative) levels measured in 2006. We noted in past reports that concentrations in the installation FJC are subject to relatively large variability, approaching that seen in the removal FJC. There have been sudden increases in this FJC over the years (e.g., in 1999 and 2006), but typical concentrations fall in the range 0.2 to 0.4 f/ml. The average fiber concentrations in 2020 and 2021 are somewhat less than that given by the regression

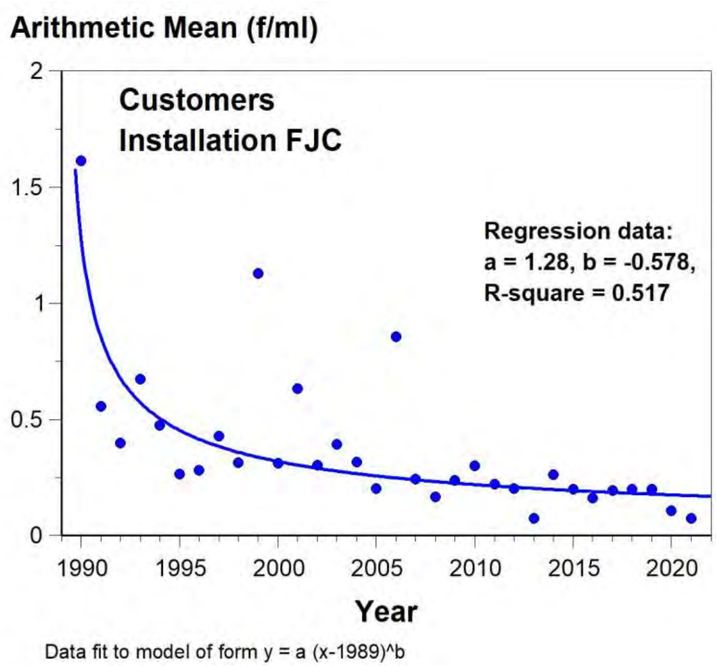



**FIG. 20.** *Average TWA fiber concentration trend in installation FJC at customer facilities.*

line shown in Figure 20. Sample sizes in both years were small (only 10 samples in 2020 and 8 samples in 2021), and only a small number of installation operations were monitored.

Aside from years such as 1999 and 2006, the regression model fits the data fairly well, and predicts average concentrations between 0.2 and 0.4 f/ml in the near future. Current levels are beneath this range, probably because of limited monitoring during the COVID-19 pandemic. As in most other FJCs, the largest decrease occurred early in the program, with more modest decreases in recent years.

Not all FJCs among customers fit the regression model as well as those presented above. Figure 21, for example, shows the time trend for the removal FJC from 1990 to 2021.

Here the variability is extremely high, with very large year-to-year swings in average TWA concentrations. Given this amount of variability, very long periods of monitoring will be required to reliably establish a time trend in this FJC. We expect to see large swings in the average TWA for removal operations in future years. The $R^2$ value (0.1) is quite low, indicating that the learning curve model explains very little of the observed variability. Indeed, there appears to be no obvious pattern in data points plotted in Figure 21. The learning curve model was fit to these data only because it was found useful for exposures in other FJCs and for the weighted-average exposures.

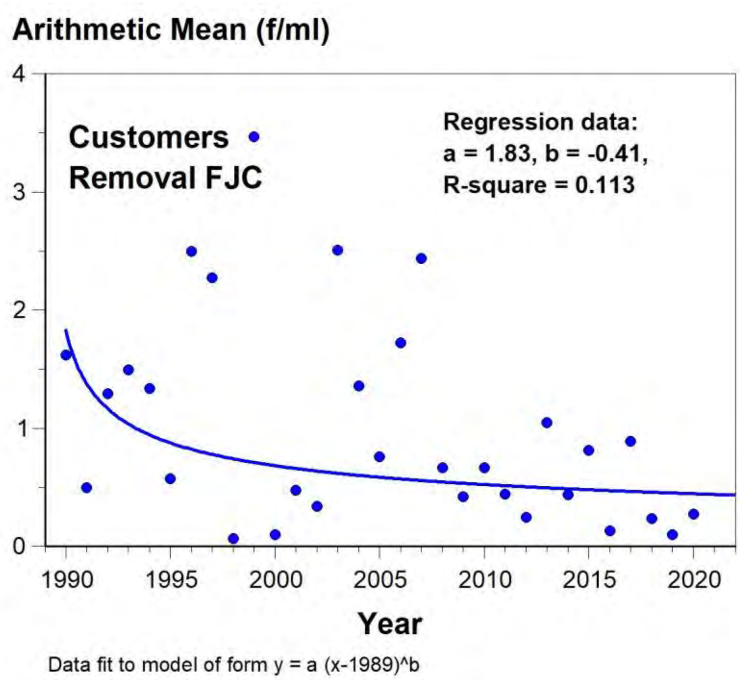



**FIG. 21.** *Average TWA fiber concentration trend in removal FJC at customer facilities.*

The average TWA concentration for removal in 2020 (approximately 0.27 f/ml) was below the trend line and significantly less than the value recorded in 2017 (0.89 f/ml). No removal samples could be collected in 2021, as discussed above. Exposures in this category are usually controlled by use of respirators because in most cases it is not possible to apply engineering controls.[54]

One FJC at customer facilities suggests a slight downward trend with highly variable exposures since 1990. Figure 22 plots these data for the mixing/forming FJC at customer facilities. The overall trend since 1990 based upon this regression has historically been *upward*, but the $R^2$ value was very low (0.0004) in 2015. In 2016, the trend reversed and the overall trend was slightly downward (the slope of the model is very slightly negative) although the $R^2$ value was still low (0.002) indicating that the regression model explained very little of the observed variability. In 2021 the trend remains slightly downward, and the $R^2$ value remains low at 0.04.

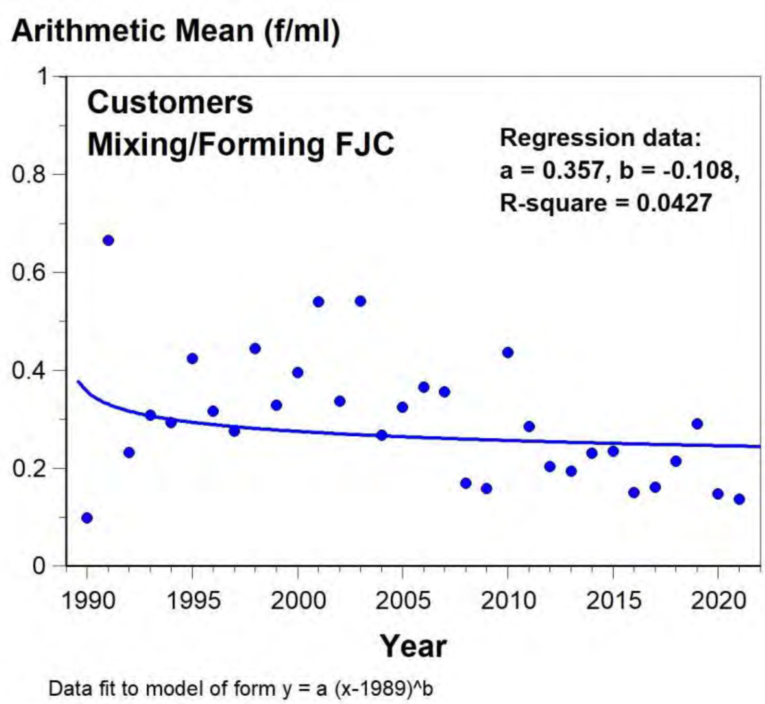
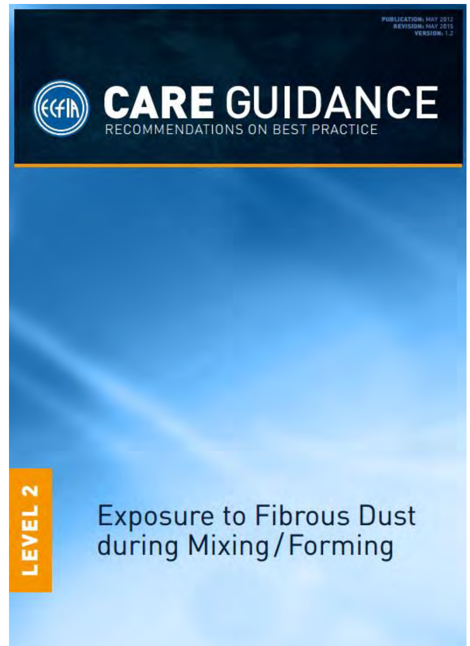



**FIG. 22.** *Average TWA fiber concentration trend in mixing/forming FJC at customer facilities.*

[54] In recent years, we have seen some limited application of engineering controls to mold knockout and kiln car removals. These are small-scale operations that allow use of dust booths or local exhaust ventilation. Such control measures are not applicable to large furnace or kiln removals.




During PSP 2017, concentrations rose from 0.16 f/ml in 2017 to 0.29 f/ml in 2019, then fell to 0.14 f/ml in 2021. Since about 2000, the overall trend appears to be downward (though highly variable). Even though data collected since 2016 have caused the model to also trend downward, long time periods will be required to reliably demonstrate any trend in this highly variable category.

Both the regression estimate of the average TWA in this FJC (0.25 f/ml) and the average measured concentration (0.14 f/ml) were beneath the REG in 2021. This FJC represents a relatively small fraction of the customer workforce (approximately 4%). Still, the HTIW Coalition member companies continue to watch exposures in the mixing/forming FJC closely to see if exposures remain beneath the REG. The fact that concentration levels in this FJC have shown little improvement on average (despite the relatively low levels) has prompted RCF producers to develop a guidance document in May 2014 intended to help customers reduce levels further. It is available on the ECFIA website at https://ecfia.eu/wp-content/uploads/2018/12/ECFIA-CARE_Guidance-Level_2-Mixing_Forming.pdf.

### *-Weighted Averages*

Trends in the weighted average are likely to be of greatest interest to readers because all of the data are included (appropriately weighted), and thus the aggregate sample size is largest, which smooths year-to-year fluctuations in each of the FJCs. Figure 23 shows that the weighted average TWA concentrations among customers have decreased from approximately 1.14 f/ml in 1990 to 0.06 f/ml in 2021—a decrease of approximately 95%. The decrease in average exposure provides additional evidence of overall success in the HTIW Coalition stewardship program. We have shown in earlier sections of this report that occasional setbacks in some FJCs are common, and downward trends are not constant. In 2021, the weighted average for customers decreased sharply from the level measured in 2020, and was substantially beneath the REG/REL.

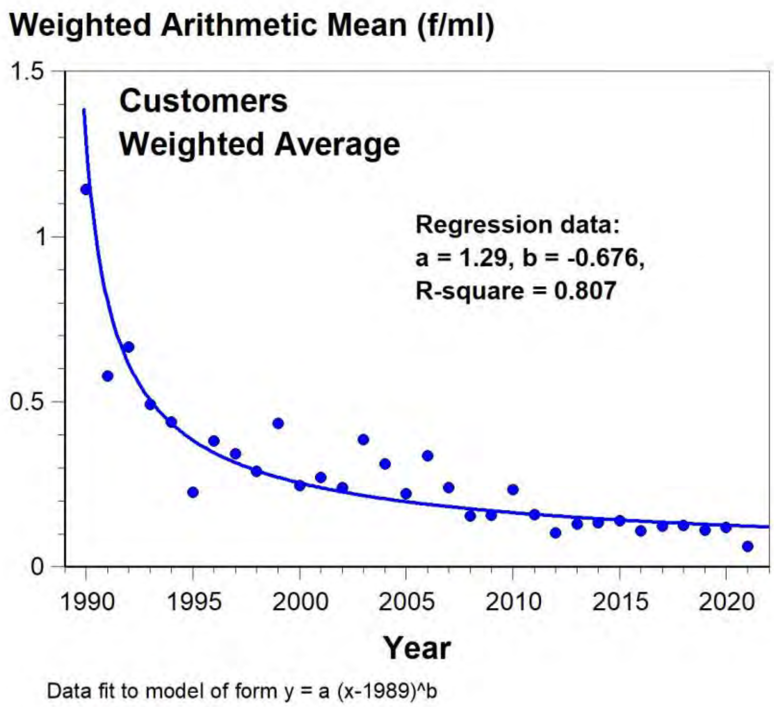



**FIG. 23.** *Time trend in weighted average TWA concentrations at customer facilities.*

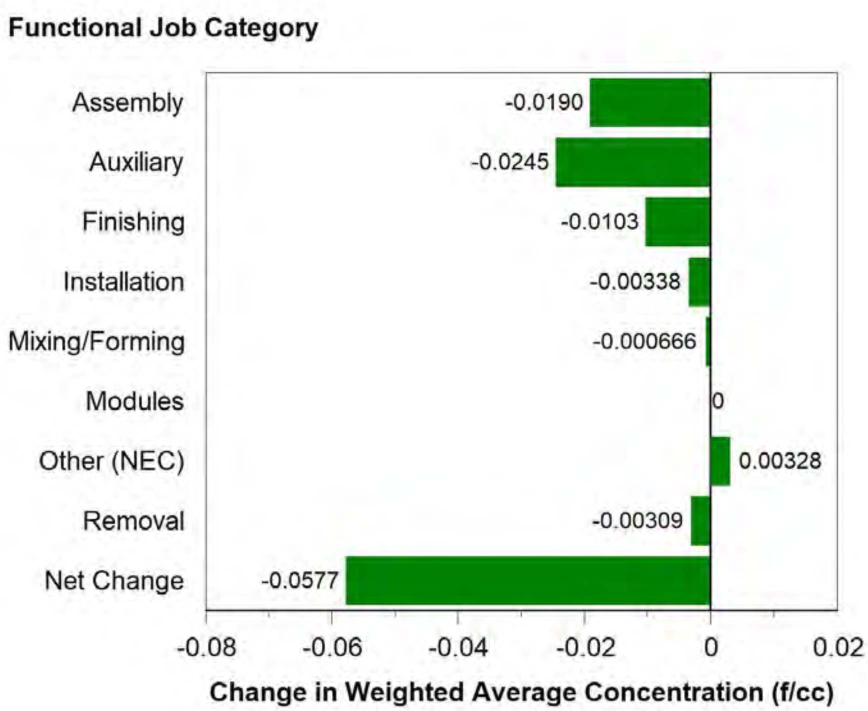



**FIG. 24.** *Components of change in weighted average TWA fiber concentration at customer facilities, 2020-2021.*

Figure 24 illustrates the individual FJC contributions to the observed decrease from 2020 to 2021. This illustration shows that most of the decrease in 2021 compared to 2020 can be attributed to decreases in the assembly and auxiliary categories.

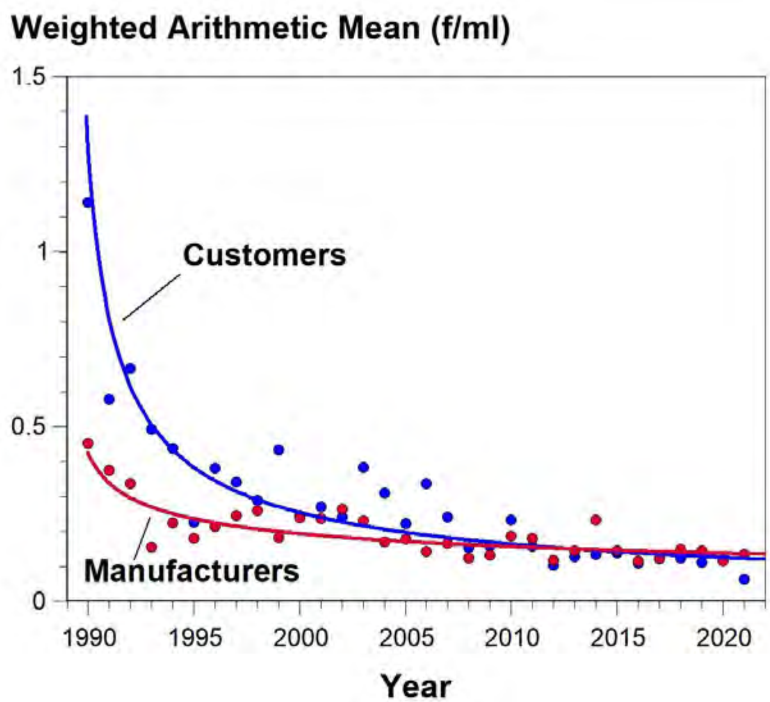



**FIG. 25.** *Time trends in weighted average TWA concentrations at manufacturer and customer facilities, 1990-2021.*

### *-Manufacturers and Customers Compared*

Figure 25 shows the weighted average time trends for manufacturers and customers on a single graph. Although the weighted average fiber concentration regression estimate for customers was historically greater than that among manufacturers (in part because customers engage in certain activities, such as removal of after service insulation that result in relatively high exposures), the decrease from 1990 to the present has been greater than the corresponding decrease among manufacturers. The gap between manufacturers and customers has decreased over time,[55] and in recent years the predicted concentrations for customers has fallen below that of

[55] In fact, the weighted average for customers has been *lower* than that of manufacturers for several years, but the differences were small prior to 2021. The difference is larger in 2021, but sample sizes in 2021 are small so this may be a temporary occurrence; this comparison will be revisited in future reports.

manufacturers. The curves indicate that more rapid learning has taken place among customers than manufacturers over this period. The extra learning probably reflects the fact that customers are implementing approaches already proven by the manufacturers.

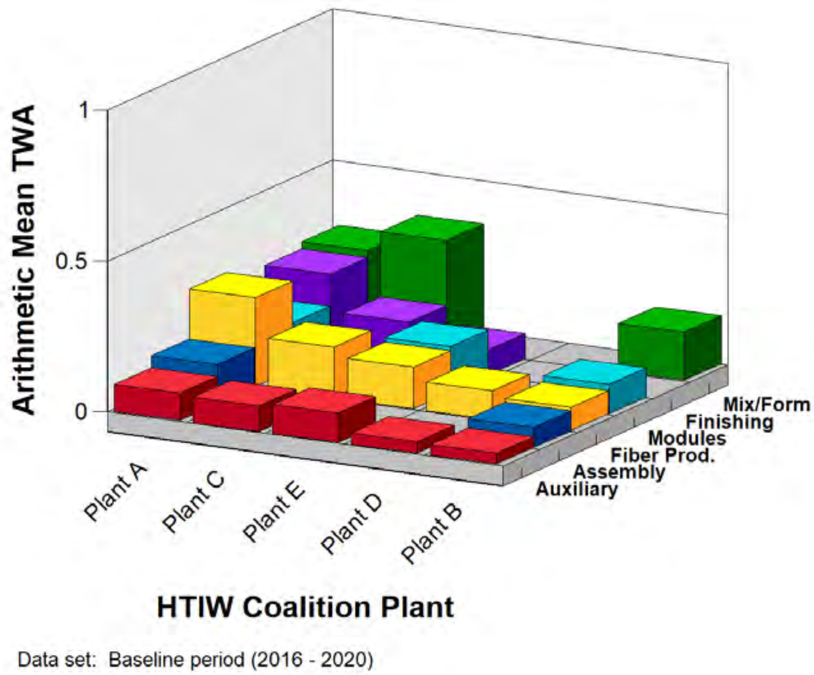



**FIG. 26.** *Benchmarking comparisons, baseline period.*

## Benchmarking

Benchmarking is a key technique included in PSP 2017. Benchmarking involves a systematic comparison of performance (in this case, fiber concentrations) across plants in the industry. PSP 2017 benchmarks in two ways:

- For fiber concentration measurements at plants operated by HTIW Coalition members, exhibits similar to that shown in Figure 26 (referred to as "skyline charts" because of their similarity to a cityscape) are prepared.[56] This particular graph shows the average

[56] In prior reports (e.g., PSP 2012 reports), the benchmarking analysis included three fiber-producing plants. As noted in earlier PSP 2017 reports, Nutec and HarbisonWalker International joined the HTIW Coalition as associate members, and have become full members in 2022. Benchmarking exhibits now show five fiber producing plants.

fiber concentrations in several FJCs at plants where RCF is manufactured over the five-year baseline period (plants are ranked by the average concentration in the fiber production FJC). As can be seen, there are clear (and statistically significant) exposure differences among plants for several FJCs. These data are shared by HTIW Coalition members who try to understand reasons for observed differences and to identify best practices.

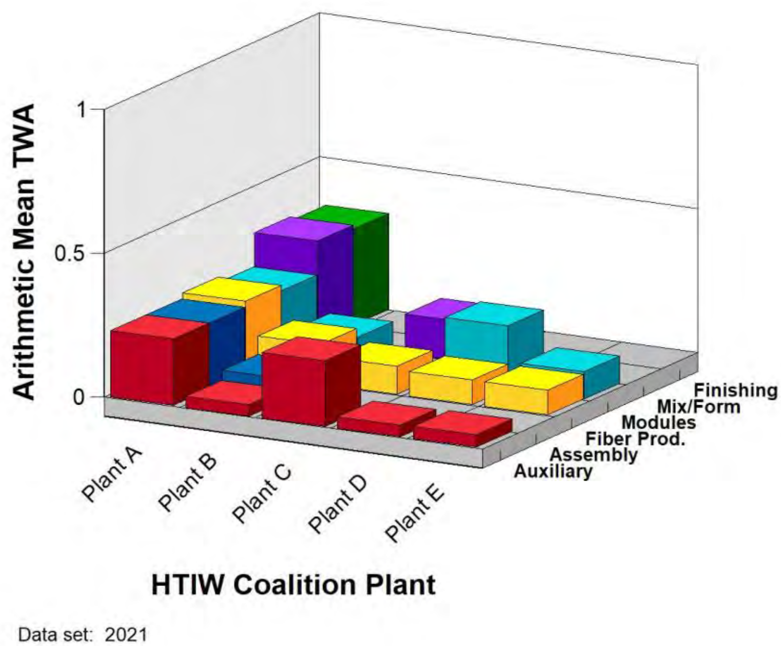



**FIG. 27.** *Benchmarking comparisons, 2021.*

- Figure 27 shows the same plot for 2021. Note the rank order of plants is different relative to the baseline period; this is not uncommon—small changes in the rank order of plants occur as a result of variability in the data. Average TWA concentrations are well beneath the REG in 2021.
- It should be noted that the data presented in Figure 27 are *not* corrected for respirator use. In fact, some workers in nearly all FJCs at Plant A wore respirators on the day of monitoring in 2021. Workers in plants B and E rarely wear respirators because measured TWA concentrations have been reliably beneath the REG in the past.

- Figure 28 shows the arithmetic mean TWA for the same set of data shown in Figure 27 but is corrected for respirator use. On average, workers were not overexposed to RCF at these plants in 2021 based upon measured airborne concentrations; when the effects of respirators are considered, exposures are well beneath the REG. Note that the rank order of plants has changed—plant A (where respirators are worn regularly) now ranks lower than plant B (where respirators are rarely used because of reliably low measured exposures).

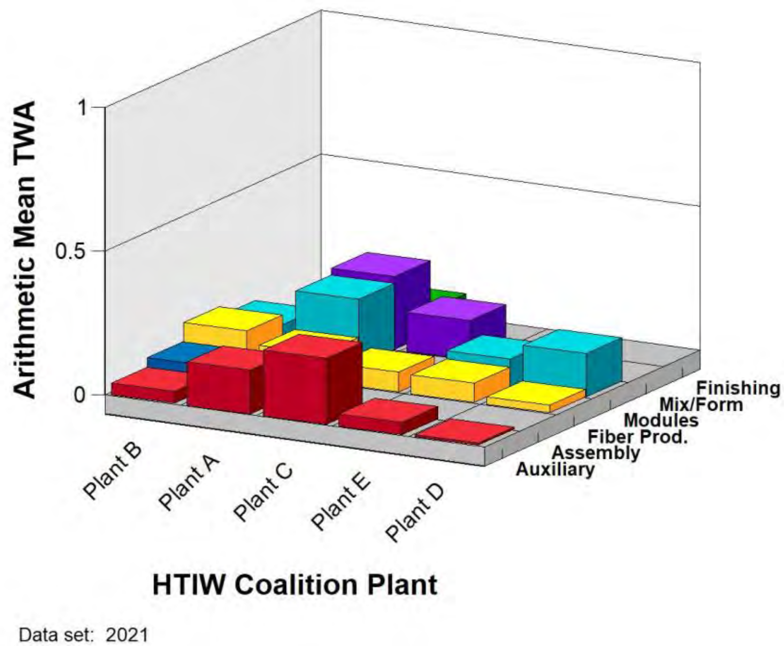



**FIG. 28.** *Benchmarking comparisons, 2021, adjusted for respirator use.*

- For fiber concentration measurements at customer facilities, statistical summaries are prepared by FJC and included in reports sent to facilities monitored, posted on the web, and included in the standard package of literature sent to customers, which enables each customer to understand how its facility compares to others in the same FJC. In other words, monitoring results are compared not only to the established REG, but also to average concentrations among customers in each FJC. Figure 29 is an example of a "ladder diagram," which shows the percentiles of monitoring data in each FJC for the latest 5-year period (2017-2021 in this example). Using this data summary, customers can evaluate their performance relative to other customers performing similar tasks. The ladder diagram is included in any monitoring report prepared for the customer.

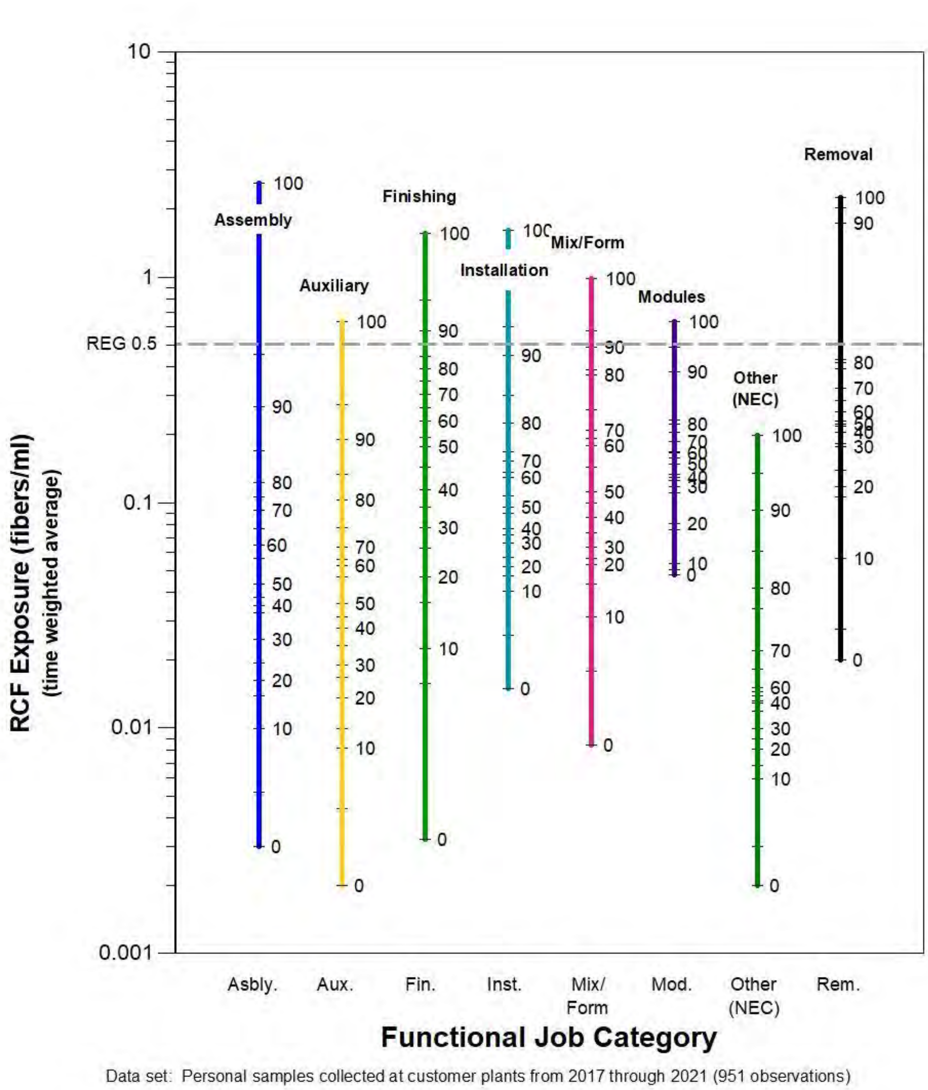



**FIG. 29.** *"Ladder diagram" showing RCF exposures, customers, 2017 through 2021.*

## Quality Assurance/Quality Control

As part of the PSP 2017, the HTIW Coalition member companies adopted and continue to use the quality assurance plan developed and submitted to OSHA as part of PSP 2002. This quality assurance plan has not been revised.

A sampling audit for 2021 was conducted at a manufacturing plant operated by Morgan Thermal Ceramics. For reference, a blank sample data collection sheet is included in Appendix C.

W.M. Ewing & Company LLC[57] of Marietta, GA, completed an audit of a fiber sampling protocol at the Morgan Thermal Ceramics manufacturing plant in Augusta, GA on February 1, 2022. No material or even minor discrepancies were noted and no corrective actions were recommended. The auditor stated, "Based observations made during this audit, the sampling procedures used will provide reliable, representative data for the activities monitored and there are no recommendations for changes to the procedures." The audit also noted that the Industrial Hygienist conducting the sampling was knowledgeable regarding sampling protocols and QAPP requirements. The result of the audit is attached in Appendix B.

The HTIW Coalition was not required to conduct a laboratory audit in 2021. An audit of the currently used phase contrast microscopy (PCM) laboratory at Bureau Veritas (formerly Clayton Environmental Laboratory) in Kennesaw, GA was conducted in September 2006 as part of the PSP 2002 Agreement which eventually became PSP 2012, and subsequently PSP 2017. At that time, no material discrepancies were noted and this laboratory continues to operate with full accreditation (see https://www.bvna.com/environmental-ih-laboratories/resources/certifications-accreditations).

## Customer Service Activities

Customer service activities under PSP 2017 encompass a number of different forms of outreach to customers. Several examples of these activities are described in this section.

The HTIW Coalition member companies continue to develop and communicate best work practices, develop Safety Data Sheets and labels pursuant to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (as implemented by OSHA in its amendments to the Hazard Communication Standard), and promote continuous improvement in the appropriate handling and use of RCF through employee and customer involvement. The following types of information are communicated:

[57] Online at https://ewingcih.com/.

- Narrative reports on the most effective control measures and work-practices identified
- Document customer work practice changes using questionnaires, personal visits, or other measures,
- Document number of individuals or companies requesting on-site training, monitoring, or other assistance,
- Track number of hits on the HTIW Coalition's website, and
- Track number of incoming inquiries to the HTIW Coalition and company health and safety information numbers.

In reference to the above, HTIW Coalition's responses are as follows:

- *Reports:* In 2015 RCF manufacturing companies began using the North American Hazard Classification System and Warning Labels for RCF and other fiber-based products on or before the effective date of June 1, 2015. This change in labelling was driven by the new OSHA HazCom 2012 regulation which specifically defines how products sold in North America must be labeled. RCF manufacturers worked with manufacturing employees, salespeople, and customers to implement the change in labels, ensure compliance with the new regulations, and offered training on the requirements of the new regulations. Manufacturers continued to use the new labeling system and offered guidance to customers through 2021.
- There were no new magazine or journal style reports issued on the use and safety of RCF materials. In the past, information has been disseminated to users via *Workplace Quality News* (a newsletter published by Unifrax prior to becoming Alkegen) and conferences sponsored by HTIW Coalition members and from the HTIW Coalition website. The most recent reports were on the changes associated with the California OSHA PEL in 2010. Of course, the HTIW Coalition and its member companies sponsor the research published by the team at the University of Cincinnati. Narratives and information developed for earlier PSP programs are also on the HTIW Coalition website.
- *Customer work practice changes:* There is no new information to report in 2021, but the issue will be addressed in the future as circumstances warrant.

- *Document number of customer inquiries:* As discussed above, the coding necessary for generating statistics on web traffic was inadvertently removed from the Coalition's webpage during website updates or maintenance; the Coalition is therefore unable to provide these statistics in this report. The coding issue will be addressed so that website statistics can be included in future reports. As noted above, websites maintained by ECFIA and individual companies also contain PSP information. In prior years, HTIW Coalition member companies provided printed literature to interested parties, including handling guidelines, reports, multimedia presentations, MSDS sheets, issues of *Workplace Quality News,* and related material. Member companies have moved away from providing printed materials about RCF and have been directing interested parties towards member company websites and http://www.htiwcoalition.org/. Member companies are now delivering safety information with product invoices. As a result, no written materials were sent out via mail in 2021.
- *Hotline calls:* The same is true for hotline or other telephone calls. Member companies are moving away from older methods of delivering information and relying instead on the internet to provide information. In 2021, only 30 calls were taken via telephone. This number is expected to continue to decrease in subsequent years as more information is provided via company websites.

Other ongoing customer service activities include disseminating information on respirator manufacturers and respirator fit testing. The HTIW Coalition has posted a document online[58] that helps customers to identify respirator manufacturers and distributors that provide respirator fit testing and training. Contact information (telephone numbers and website addresses) for major respirator manufacturers and distributors is provided so that customers can contact the companies directly and request information about obtaining respirator fit testing and training locally.

HTIW Coalition members also consult with customers who are concerned about overall fiber exposure and make recommendations to improve engineering controls for airborne fiber generation and local ventilation. Although there is nothing to report on this topic for 2021, specific consultations have been discussed in previous annual reports to OSHA.

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[58] See http://www.htiwcoalition.org/documents/GuidanceOnObtainingRespirators_2018.pdf

## Product Research

As part of PSP 2017, the HTIW Coalition and its member companies continue to encourage research to develop new and improved HTIW product forms. PSP 2017 notes that HTIW product research generally focuses on two key elements, dose and dimension:

- **Dose:** Dose can be reduced through other stewardship efforts aimed at exposure control. From a product perspective, dose can also be reduced through encapsulation of RCF-containing materials. Several RCF products, such as the Firemaster FastWrap® duct insulation, are sold in encapsulated forms.
- **Dimension:** HTIW Coalition members have investigated the potential to change the dimensions (principally the diameter) of RCF fiber to reduce the fraction in the respirable range (< 3 *microns* [μm]) while maintaining key performance properties. To date these efforts have not proven successful. While it is possible to increase the nominal diameter of the fibers, the thermal properties of the resulting product are degraded; specifically, the thermal conductivity increases, reducing the efficiency of the product. As well, larger diameter fibers appear to be more irritating to the skin.

A third element, *durability*, is largely a function of composition. The industry has developed alternative fibers, termed *alkaline earth silicate* (AES) wools, which are less durable (in *in vitro* systems) and less biopersistent (in *in vivo* animal experiments) and functionally capable of being substituted for RCF in certain applications.

There have been no noteworthy RCF product research developments in the past year.

## Consumer Products

As part of PSP 2017, the HTIW Coalition member companies continue to use their best efforts to ensure that exposures in consumer product applications are well controlled. HTIW Coalition members go through a systematic procedure to screen potential consumer applications.[59]

Use of RCF in a consumer product in a manner that may cause significant exposure, under proper use and maintenance conditions, is deemed to be inconsistent with the intent of PSP 2017.

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[59] See e.g., Venturin, D., *et al*., (1997). Qualitative industrial hygiene life cycle analysis applied to refractory ceramic fiber (RCF) consumer product applications. *Reg. Toxicol. Pharmacol.*, 25: 3, 232-239.

RCF is chiefly an industrial product and no consumer applications for RCF have been developed in the past year.

## Waste Minimization and Disposal/Environmental Responsibility

As part of PSP 2017, the HTIW Coalition member companies continue to:

- Study, recommend, and implement waste minimization programs designed to reduce quantities of waste produced per unit of product and to increase recycling rates where practicable and effective.
- Design and/or modify their processes so as to minimize consumption of natural resources and energy and to eliminate, to the extent feasible, the generation of waste materials and releases to the environment. In so doing, the companies will continue to focus on source reduction as the preferred approach to waste management, followed by internal recycle/recovery. Treatment and/or disposal are employed as a last resort.

The hierarchy of methods for waste reduction; (i) source reduction, (ii) increased internal recycle/recovery, (iii) treatment or disposal—makes good economic as well as environmental sense. Thus, other things being equal, it is more efficient economically to increase process yields than recycle rates, because (compared to increased recycling) increased yields not only reduce raw material requirements and waste handling costs, but also process and energy requirements and internal recycling costs per unit of finished product. And, of course, wastes by definition are non-productive. It should be noted that increased yield and recycling rates have beneficial impacts throughout the entire life cycle, not just at RCF manufacturing plants. Thus, for example, increased process yields mean that less alumina and silica are used per unit of finished product, avoiding environmental impacts in these stages of production.

Process waste streams are generated (to varying degrees) at several stages of RCF production and conversion, from fiber manufacture through finishing operations. In the main, these waste streams are solid wastes (e.g., shot, edge trim, *etc.*); air emissions and wastewater volumes are minimal. For economic and other reasons the industry has worked hard to increase yields and recycling rates in each stage. RCF producers have been quite successful in this regard.

Both process yields and solid waste recycling rates have increased over the years.[60] Details of these process improvements are regarded as proprietary. However, the amount internally recycled (among all producers) amounts to several million pounds per year.

Energy is used in the production of RCF at several stages and energy price increases create a strong economic incentive for potential insulation customers to become more energy efficient. Morgan Thermal Ceramics continued to implement a global *Energy and $CO_2e$*[61] *Reduction Program* in 2021.[62] The objectives of this initiative include:

- 50% reduction in $CO_2e$ emissions by 2030,
- Reduce energy consumption and energy wastes,
- Reduce energy intensity of manufacturing processes,
- Optimize processes for energy efficient operation,
- Increase clean/green energy and/or renewables, and
- Increase use of renewable energy credits, if available

Alkegen also has an active program to reduce waste and energy use. In 2015, initiatives were developed to conduct audits on waste material, encourage local and corporate level recycling programs, and identify ways to reduce overall power consumption. Key aspects of Alkegen's current energy and waste reduction efforts include:

- Products that reduce fossil fuel consumption,
- Reduce waste and energy consumption by 2-3% annually,
- Develop internal metrics, benchmarking, and opportunity analysis around energy usage and emissions reduction, and
- Goals will be set and shared publicly

[60] The most recent report on this subject is Everest Consulting Associates (1995). *Waste Generation and Management in the Manufacturing, Processing, and Use of Refractory Ceramic Fiber*. Submitted to the US Environmental Protection Agency. Everest Consulting Associates, Princeton Junction, NJ.

[61] $CO_2$ equivalent, defined as the number of metric tons of $CO_2$ emissions with the same global warming potential as one metric ton of another greenhouse gas.

[62] The program was initiated in 2007.

Over the final two years of PSP 2017, the United States (and most other countries worldwide) experienced significant workplace restrictions and business interruptions resulting from the COVID-19 pandemic. The RCF industry has not been immune from the effects of the pandemic; many workers were furloughed, and some were laid off. Yet, it is important to note that through the economic turmoil of the past few years, the RCF industry has remained committed to the principles of PSP 2017. Industry executives believe and have demonstrated that health and safety is a core value for the industry. Former ALCOA CEO and U.S. Secretary of the Treasury, Paul O'Neill, perhaps said it best when he said:

"Safety is not a 'top priority.' Safety is a precondition."[63]

## Compliance Principles

In an attempt to clarify PSP compliance issues for future reference, the HTIW Coalition has prepared a compliance principles statement (the document, reviewed by OSHA, was added to the online PSP documentation in 2015[64]). The general principles are all based on current or longstanding OSHA regulations or policies. Readers are referred to the online document for details; in summary, the principles state:

- The Compliance Principles document was developed by the HTIW Coalition, and reviewed by OSHA staff,
- The principles expressed are based on current OSHA regulations and policies,
- Compliance is required with all applicable OSHA standards (e.g., respirators),Requires calculation of confidence limits for sampling results (per OSHA Technical Manual),
- Allows determinations based on *objective data* (as defined in the final crystalline silica standard[65]), and
- Applies OSHA policy for respiratory hazards not covered by PELs: the REG and the NIOSH REL (both currently 0.5 f/ml) are recommendations, not PELs, and should not be enforced as PELs.

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[63] See http://www.ishn.com/articles/treasury-chief-gets-blunt-about-safety.

[64] Revised in 2019; available online at http://www.htiwcoalition.org/documents/PSP%20Compliance%20Principles%20Feb%202019.pdf.

[65] 81 Fed. Reg. 16710 (March 25, 2016)

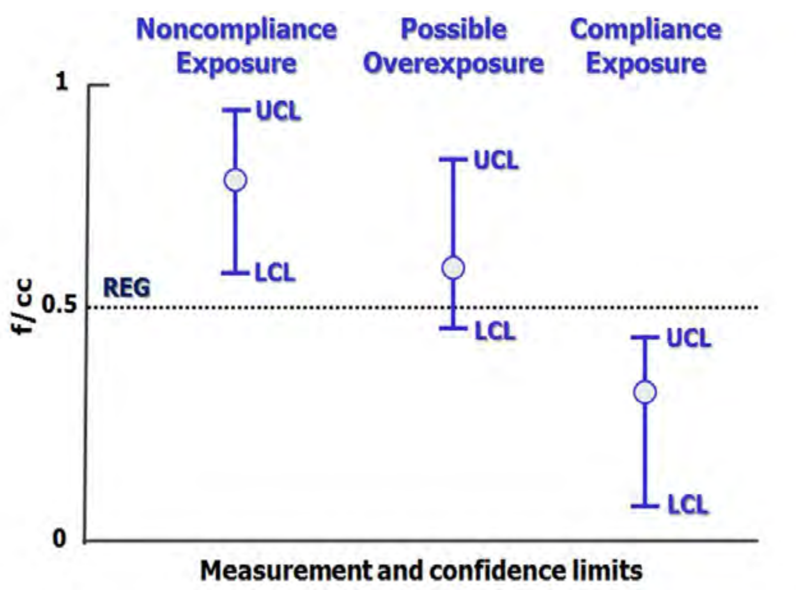


**FIG. 30.** *Compliance with the REG including confidence limits, per the OSHA Technical Manual.*

The HTIW Coalition member companies, through the Product Stewardship Program, have conducted workplace monitoring for nearly 30 years. The exposure data collected over this period now forms an extensive database with samples that represent nearly all current RCF workplace activities. These samples can be used as objective data to generate the upper and lower confidence limits required for determination of compliance with the REG. Figure 30 illustrates compliance determination based on the OSHA Technical Manual. Noncompliance exposure requires both the *upper confidence limit* (UCL) and the *lower confidence limit* (LCL) to exceed the REG.

## Reporting

The HTIW Coalition and its member companies have committed to delivering annual reports to OSHA to document progress on PSP 2017 and to generate a detailed report at the end of the five-year program. This report fulfills the requirement for a fifth annual report under PSP 2017.

# APPENDIX A:

## Publications

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SHORT COMMUNICATION

Journal of Applied Toxicology WILEY

# Mortality of workers employed in refractory ceramic fiber manufacturing: An update

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## Abstract

This study evaluates the possible association between refractory ceramic fiber (RCF) exposure and all causes of death. Current and former employees ($n = 1{,}119$) hired from 1952 to 1999 at manufacturing facilities in New York (NY) state and Indiana were included. Work histories and quarterly plant-wide sampling from 1987 to 2015 provided cumulative fiber exposure (CFE) estimates. The full cohort was evaluated as well as individuals with lower and higher exposure, <45 and ≥45 fiber-months/cc. The Life-Table-Analysis-System was used for all standardized mortality rates (SMRs). Person-years at risk were accumulated from start of employment until 12/31/2019 or date of death. There was no significant association with all causes, all cancers, or lung cancer in any group. In the higher exposed, there was a significant elevation in both malignancies of the "urinary organs" (SMR = 3.59, 95% confidence interval [CI] 1.44, 7.40) and "bladder or other urinary site" (SMR = 4.04, 95% CI 1.10, 10.36), which persisted in comparison to regional mortality rates from NY state and Niagara County. However, six of the nine workers with urinary cancers were known smokers. In the lower exposed, there was a significant elevation in malignancies of the lymphatic and hematopoietic system (SMR = 2.54, 95% CI 1.27, 4.55) and leukemia (SMR = 4.21, 95% CI 1.69, 8.67). There was one pathologically unconfirmed mesothelioma death. A second employee currently living with a pathologically confirmed mesothelioma was identified, but the SMR was non-significant when both were included in the analyses. The association of these two mesothelioma cases with RCF exposure alone is unclear because of potential past exposure to asbestos.

KEYWORDS

bladder, cancer, lung, man-made vitreous fibers, mesothelioma, refractory ceramic fibers, synthetic vitreous fibers, urinary

## 1 | INTRODUCTION

Refractory ceramic fibers (RCFs) are produced from alumina and silicon dioxide or kaolin and are one type of man-made vitreous fibers (MMVFs). With high heat resistance, durability, and tensile strength, RCFs have commercial and domestic uses including high-temperature insulation for furnace linings in the chemical, petrochemical, foundry, steel, and forging industries. Air concentrations, especially from 1990 to 2010, were highest for those engaged in removal/replacement activities of RCF furnace linings, and in 2002, respiratory protection was required for these activities (Maxim & Utell, 2018; National Toxicology Program [NTP], 2016). A recent study of Chinese RCF workers ($n = 430$) compared with controls ($n = 121$) indicated that cumulative RCF and dust exposure levels in a non-dose-dependent manner were associated with altered levels of lung biomarkers (CC16 and TGF-β1) and oxidative stress markers (8-OHdG) (Gu et al., 2020). The International Agency for Research on Cancer (IARC) classified RCF as 2B, possibly carcinogenic to humans (IARC, 2002). Animal inhalation studies prior to the 1987 initiation of the current study (Davis et al., 1984; Smith et al., 1987) and subsequent animal studies documented both pleural and interstitial changes as well as lung cancer and mesotheliomas raising concerns about the potential impact of RCF exposure on humans (Mast, McConnell, Anderson, et al., 1995; Mast, McConnell, Hesterberg, et al., 1995; McConnell et al., 1995). To our knowledge, the present research is the only mortality study of RCF-exposed workers. Our prior analyses have not identified an association between respiratory cancers and RCF (LeMasters et al., 2017). The purpose of the present study is to update our previous findings, provide details regarding a second mesothelioma case in the cohort, and for the first time, evaluate differences in cancers between higher and lower RCF exposure groups.

## 2 | MATERIALS AND METHODS

### 2.1 | Study population

Current and former male and female employees ($n = 1{,}119$) were included who were hired from 1952 through 1999 with at least 1-year employment at two RCF manufacturing facilities located in New York (NY) state ($n = 818$) and Indiana (IN) ($n = 301$). Complete work histories were available by interview (91.6%) or company records (8.4%). Thirty-five were deceased at study initiation. Cause of death was determined by death certificate coded by a nosologist until 2010 and then by the National Death Index (NDI) Plus through 2019. International Classification of Diseases (ICD) did not have a code for mesothelioma until ICD 10 beginning in 1999. Before this date, pleural cancers could be used to approximate the observed number of mesothelioma deaths, although there were none. From 1987 until 1993, occupational, health, and smoking histories were updated yearly and then every 3 years through 2014. Participants signed an informed consent approved by the University of Cincinnati Institutional Review Board. Since our previous publication with 234 accumulated deaths through 2014, there are an additional 76 deaths and one additional living mesothelioma case (LeMasters et al., 2017).

### 2.2 | Exposure assessment and RCF exposure categories

Historical exposures were reconstructed from available industrial hygiene information and measurements and plant-wide sampling conducted quarterly from 1987 through 2015. Both were used for cumulative fiber exposure (CFE) estimates (Rice et al., 2005). On the basis of these data, participants were previously divided into four exposure categories (0–15, >15–45, >45–135, and >135 fiber-months/cc), each having a mean value statistically significant from one another as described elsewhere (Lockey et al., 2002). For the current analyses, exposure categories were combined into higher (≥45 fiber-months/cc) and lower (<45 fiber-months/cc) groups. Exposures were not measured for sales jobs, as their activities varied widely from office work to on-site industrial teardown and installation operations in multiple communities. Asbestos was not used in product manufacturing at study locations. Activities with other potential occupational or home asbestos exposure were reviewed with participants during a detailed interview that included such activities as wearing asbestos gloves or changing brake linings. A few hours of reported exposure were rounded to the lowest cumulative asbestos exposure category of 1 month.

### 2.3 | Statistical analysis

The Life-Table-Analysis-System Version 4.5 (LTAS) (Schubauer-Berigan et al., 2011) was used, incorporating reference mortality rates from the entire United States, NY (excluding NY City), Niagara County (NY), IN, and St. Joseph County (IN). The LTAS uses a general population comparison group and standardized mortality rates (SMRs) are generated. Person-years at risk were accumulated from start of employment until 12/31/19 or date of death, whichever occurred first. Person-years at risk were stratified by age, race (white, other), gender, and calendar year. SMRs were computed for the full cohort ($n = 1{,}119$), the higher ($n = 290$), and lower ($n = 567$) exposure groups. Excluded from the higher and lower exposure group analyses were those with any sales history ($n = 124$), only office work ($n = 121$), incomplete work histories ($n = 10$), or employment at non-study sites ($n = 7$) with possible, but undocumented RCF exposure. These exclusions eliminated 43 of 310 deaths (13.9%) from the higher and lower exposure group analyses. To evaluate differences in characteristics of the study subjects, $t$ tests were used.

## 3 | RESULTS

### 3.1 | Demographics

As shown in Table 1, the vast majority of the 1,119 participants were White and male and had a mean age of 65.2 years at end of follow-up (living) and 68.2 at time of death (deceased). Depending on their living/deceased status and exposure category, those having ≥30 years since hire (latency) ranged from 59.7% (deceased/lower exposure) to 94.2% (living/higher exposure) (Table 1). There were 310 deceased (27.7%) in the full cohort. After exclusion of the aforementioned 43 deaths, there were 118 (40.7%) and 149 (26.3%) deaths in the higher and lower exposure groups, respectively (Table 1). The deceased compared with the living in both exposure groups were significantly more likely to have higher mean pack years of smoking, an earlier date of hire and higher CFE but reduced cumulative person-years of observation and mean work duration (Table 1). The mean year of hire for the higher versus lower exposed deceased was 1967

**TABLE 1** Characteristics of study subjects

| Characteristic | Full cohort living | Full cohort deceased | ≥45 fiber-months/cc living[a] | ≥45 fiber-months/cc deceased[a] | <45 fiber-months/cc living[a] | <45 fiber-months/cc deceased[a] |
|---|---|---|---|---|---|---|
| Number | 809 | 310 | 172 | 118 | 418 | 149 |
| Cumulative person-years of observation | 29,809 | 10,306 | 7,387 | 4,384 | 14,467 | 4,610 |
| Crude proportion of deaths (%) | 27.7 | | 40.7 | | 26.3 | |
| Male gender (%) | 80.0 | 93.2 | 91.3 | 98.3 | 81.8 | 92.6 |
| White race (%) | 90.9 | 92.3 | 86.8 | 94.7 | 89.5 | 88.8 |
| Mean age (years) | 65.2 | 68.2 | 68.2 | 70.4 | 63.3 | 67.2 |
| Ever smoker (%)[b] | 54.2 | 74.6 | 71.3 | 75.5 | 54.4 | 72.2 |
| Mean pack years[b] | 23.8 | 40.0 | 27.9 | 43.3 | 21.8 | 39.5 |
| Mean cumulative fiber exposure (fiber-mo/cc)[a] | 38.0 | 76.8 | 114.1 | 162.1 | 15.3 | 18.2 |
| Mean duration (years) | 14.6 | 11.7 | 24.7 | 18.7 | 11.5 | 6.6 |
| Mean latency (years) | 36.9 | 33.3 | 43.0 | 37.2 | 34.6 | 30.9 |
| Latency >20 years (%) | 100 | 81.0 | 100 | 86.4 | 100 | 79.2 |
| Latency >30 years (%) | 71.7 | 63.6 | 94.2 | 73.7 | 60.5 | 59.7 |
| Mean hire year | 1983 | 1972 | 1977 | 1967 | 1985 | 1974 |

*Note*: Values were calculated to end of follow-up (12/31/2019) for the living or date of death for the deceased.
[a]Excludes participants with any RCF sales history ($n = 124$), only office work ($n = 121$), incomplete company records ($n = 10$), or employment at non-study sites ($n = 7$). Therefore, 262 participants and 43 deaths are excluded from <45 and ≥45 exposure groups.
[b]Smoking status unknown for $n = 93$ of 1,119; mean pack years for ever smokers only.

compared with 1974 ($p < 0.01$) leading to longer latency. The median asbestos exposure was 0.25 years in all groups excluding the lower exposed deceased at 0.4 years.

## 3.2 | SMR analysis

As shown in Table 2, the SMR for all three groups for deaths from all causes and all cancers was nearly at or below 1. For the full cohort, there was one significant elevation, leukemia (SMR = 2.64, 95% confidence interval [CI] 1.26, 4.85), that remained significant when using NY (SMR = 2.50, 95% CI 1.08, 4.92) and Niagara County (SMR = 2.47, 95% CI 1.07, 4.87) rates but was non-significant for IN and St. Joseph County. This finding was related to those in the lower exposure group having a higher SMR for leukemia (SMR = 4.21, 95% CI 1.69, 8.67), which remained significant when using NY (SMR = 3.54, 95% CI 1.15, 8.27) and Niagara County rates (SMR = 3.55, 95% CI 1.15, 8.27). Malignancies of the lymphatic and hematopoietic systems were also significant in the lower exposure group for the United States (SMR = 2.54, 95% CI 1.27, 4.55) but not for either state or county.

Analyses of the higher exposure group indicated a significant elevation in malignancies of the urinary system (SMR = 3.59, 95% CI 1.44, 7.40) and bladder and other urinary site (SMR = 4.04, 95% CI 1.10, 10.36). These findings were similar for NY and Niagara County.

The SMR for the one deceased mesothelioma case in the higher exposure group was not significant (SMR = 6.61, 95% CI 0.17, 36.81) and remained non-significant at the state and county levels.

Although U.S. rates were not significant, for the full cohort, there were two deaths in Niagara County in the subcategory "malignancies of other and unspecified site uterus", (SMR = 27.23, 95% CI 3.30, 98.37) and the overall category "malignancies of female genital organs" (SMR = 8.14, 95% CI 1.68, 23.79). In the full cohort, only the significant "malignancies of other and unspecified site uterus" persisted for NY rates (SMR = 9.41, 95% CI 1.14, 33.98). One of these two cases was an office worker, and the other was included in the lower exposure analyses.

# 4 | DISCUSSION

To our knowledge, this is the only mortality study of workers exposed to RCF. In contrast to animal studies, our findings do not support an association with lung cancer. An extensive review of cohort studies of other MMVF also did not identify an increased mortality risk from respiratory cancers (Suder Egnot et al., 2020). The present study also found the SMR for deaths from all causes, and all cancers were at or below expected for the full cohort and both exposure groups.

In 2003, we first reported a significant excess of urinary cancers (SMR = 3.45) with 1.45 expected and five observed (LeMasters et al., 2003). Over a 20-year period, urinary cancer mortality has

**TABLE 2** Observed deaths and standardized mortality ratios for all RCF workers and those with ≥45 and <45 fiber-months/cc

| | Full cohort ($n$ = 1,119) | | | ≥45 fiber-mo/cc ($n$ = 290)[b] | | | <45 fiber-mo/cc ($n$ = 567)[b] | | |
|---|---|---|---|---|---|---|---|---|---|
| Cause | Observed | SMR | 95% CI | Observed | SMR | 95% CI | Observed | SMR | 95% CI |
| All causes | 310 | 0.81* | 0.72–0.91 | 118 | 0.88 | 0.73–1.05 | 149 | 0.88 | 0.75–1.04 |
| All cancers | 96 | 0.95 | 0.77–1.15 | 36 | 1.03 | 0.72–1.43 | 42 | 0.94 | 0.68–1.27 |
| MN buccal and pharynx | 2 | 0.87 | 0.11–3.16 | 0 | 0.00 | 0.00–4.62 | 2 | 1.98 | 0.24–7.15 |
| MN digestive and peritoneum | 18 | 0.68 | 0.40–1.07 | 6 | 0.66 | 0.24–1.44 | 6 | 0.51 | 0.19–1.11 |
| MN respiratory | 26 | 0.79 | 0.51–1.15 | 9 | 0.77 | 0.35–1.46 | 14 | 0.97 | 0.53–1.63 |
| MN trachea, bronchus, lung | 25 | 0.79 | 0.51–1.16 | 9 | 0.80 | 0.37–1.52 | 13 | 0.94 | 0.50–1.61 |
| MN breast | 2 | 1.12 | 0.14–4.03 | 0 | 0.00 | 0.00–15.27 | 1 | 1.30 | 0.03–7.26 |
| MN female genital organs | 3 | 2.81 | 0.58–8.22 | 0 | 0.00 | 0.00–30.05 | 1 | 2.22 | 0.06–12.39 |
| MN male genital organs | 6 | 0.85 | 0.31–1.85 | 4 | 1.46 | 0.40–3.75 | 1 | 0.33 | 0.01–1.84 |
| MN urinary organs | 9 | 1.64 | 0.75–3.12 | 7 | 3.59* | 1.44–7.40 | 1 | 0.42 | 0.01–2.32 |
| MN kidney | 4 | 1.43 | 0.39–3.65 | 3 | 3.12 | 0.64–9.13 | 0 | 0.00 | 0.00–2.95 |
| MN bladder and other urinary | 5 | 1.87 | 0.61–4.37 | 4 | 4.04* | 1.10–10.36 | 1 | 0.87 | 0.02–4.82 |
| MN other and unspecified site | 14 | 0.97 | 0.53–1.63 | 5 | 1.03 | 0.33–2.40 | 5 | 0.78 | 0.25–1.81 |
| MN mesothelioma[a] | 1 | 2.29 | 0.06–12.76 | 1 | 6.61 | 0.17–36.81 | 0 | 0.00 | 0.00–19.39 |
| MN lymphatic and hematopoietic | 16 | 1.62 | 0.93–2.64 | 5 | 1.45 | 0.47–3.38 | 11 | 2.54* | 1.27–4.55 |
| Leukemia | 10 | 2.64* | 1.26–4.85 | 3 | 2.25 | 0.46–6.58 | 7 | 4.21* | 1.69–8.67 |
| Benign and unspec. MN | 1 | 0.79 | 0.02–4.38 | 0 | 0.00 | 0.00–8.38 | 1 | 1.78 | 0.05–9.95 |
| Dis. blood and blood-forming organs | 1 | 0.56 | 0.01–3.13 | 0 | 0.00 | 0.00–5.84 | 0 | 0.00 | 0.00–4.77 |
| Diabetes mellitus | 10 | 0.90 | 0.43–1.65 | 5 | 1.35 | 0.44–3.15 | 4 | 0.81 | 0.22–2.06 |
| Mental and psych. Disorders | 7 | 0.79 | 0.32–1.62 | 3 | 0.96 | 0.20–2.81 | 3 | 0.76 | 0.16–2.22 |
| Nervous system disorders | 7 | 0.56 | 0.22–1.15 | 1 | 0.22 | 0.01–1.25 | 4 | 0.73 | 0.20–1.87 |
| Heart diseases | 81 | 0.81 | 0.64–1.01 | 28 | 0.75 | 0.50–1.08 | 45 | 1.04 | 0.76–1.39 |
| Other dis. circulatory system | 21 | 0.80 | 0.49–1.22 | 6 | 0.62 | 0.23–1.35 | 13 | 1.15 | 0.61–1.96 |
| Diseases respiratory system | 32 | 1.03 | 0.71–1.46 | 15 | 1.33 | 0.75–2.20 | 14 | 1.05 | 0.57–1.76 |
| COPD | 16 | 0.91 | 0.52–1.48 | 9 | 1.44 | 0.66–2.73 | 6 | 0.80 | 0.29–1.73 |
| Diseases digestive system | 14 | 0.79 | 0.43–1.33 | 7 | 1.18 | 0.47–2.43 | 4 | 0.50 | 0.14–1.29 |
| Dis. Musculoskeletal and connective | 1 | 0.80 | 0.02–4.44 | 1 | 2.47 | 0.06–13.75 | 0 | 0.00 | 0.00–6.65 |
| Dis. Genito-urinary system | 3 | 0.41 | 0.08–1.20 | 2 | 0.77 | 0.09–2.78 | 1 | 0.32 | 0.01–1.77 |
| Sympt & ill-defined conditions | 2 | 0.42 | 0.05–1.52 | 0 | 0.00 | 0.00–2.26 | 1 | 0.48 | 0.01–2.67 |
| Tuberculosis and HIV | 0 | 0.00* | 0.00–0.72 | 0 | 0.00 | 0.00–2.41 | 0 | 0.00 | 0.00–1.52 |
| Transportation injuries | 5 | 0.48 | 0.16–1.11 | 2 | 0.57 | 0.07–2.06 | 3 | 0.61 | 0.13–1.80 |
| Falls | 3 | 0.90 | 0.19–2.64 | 2 | 1.70 | 0.21–6.13 | 1 | 0.69 | 0.02–3.83 |
| Other injuries | 4 | 0.37* | 0.10–0.94 | 1 | 0.30 | 0.01–1.67 | 2 | 0.38 | 0.05–1.38 |
| Violence | 9 | 0.66 | 0.30–1.25 | 4 | 0.91 | 0.25–2.34 | 3 | 0.47 | 0.10–1.37 |
| Other and unspecified causes | 13 | 0.98 | 0.52–1.68 | 5 | 1.17 | 0.38–2.73 | 8 | 1.34 | 0.58–2.64 |

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; MN, malignant neoplasm; SMR, standardized mortality ratio.
[a]ICD 10 C45.9 mesothelioma, unspecified (pathologically unconfirmed by research team).
[b]Excludes participants with any RCF sales history ($n$ = 124), only office work ($n$ = 121), incomplete company records ($n$ = 10), or employment at non-study sites ($n$ = 7). Therefore, 262 participants and 43 deaths are excluded from <45 and >45 exposure groups.
*Two-sided $p < 0.05$.

increased to nine. These nine workers with urinary cancer were hired between 1952 and 1977 and had a mean age of 63.2 years at time of death and a mean and median CFE of 83.8 and 95.3 fiber-months/cc, respectively. The job titles for the nine included millwright ($n = 3$), machine operator ($n = 2$), and one research technician, furnace operator, cleaner, and financial manager. Potential historical chemical exposures associated with millwright and machine operator job tasks could be an explanation for the excess urinary cancers. A significant finding by chance is yet another possible explanation. As shown in Table 2, there are a large number of mutually exclusive causes of death categories and subcategories, increasing chance significance. Studies of other MMVF do not support an association with urinary cancers (Maxim & Utell, 2018) and animal inhalation studies have not explored this potential relationship.

Another concern could be that a mortality study may not capture urinary organ cancer risk because the 5-year relative survival rate for bladder and kidney cancers is over 75%; consequently a mortality study might underestimate "true" risk (National Cancer Institute [NCI], 2021). Therefore, every 3 years between 2003 and 2014, we conducted a cancer incidence study by interviewing participants to determine if we were missing a significant number of urinary organ cancers due to survival of the cancer (LeMasters et al., 2017). Only two workers reported a urinary cancer with 6.4 expected (standardized incidence ratio = 0.31). Because the mean age at time of diagnosis for bladder cancer is 73 years, which is older than the mean age of our cohort (Table 1), we concluded that our mortality study was likely capturing most of urinary organ cancers (American Cancer Society, 2021).

Established risk factors for bladder cancer are tobacco smoking and occupational exposure to carcinogens such as in the dye and metal industries (Cumberbatch et al., 2018). Epidemiologic determinants for kidney cancers include geographic location, smoking, obesity, high blood pressure, and alcohol consumption (Scelo & Larose, 2018). Because smoking is a risk factor for urinary cancers and the deceased had considerably higher mean pack years of smoking, it may be a confounding factor. Six of the nine workers with urinary cancer had a history of smoking, and the smoking status of one is unknown. Pack years data were available for four participants and were 12.5, 29, 40, and 48. The mean year of hire for our cohort was 1972 (deceased) and 1983 (living), and their report of ever smoking was 74.6% and 54.2%, respectively. These rates are similar or lower than a large Minnesota study that showed the prevalence of ever smoking for men was 71.6% for the period 1980–1982 (Filion et al., 2012). Thus, smoking in the general population comparison group likely does not differ substantially from our cohort. Further, other malignancies associated with smoking such as buccal, pharynx, respiratory, and digestive cancers all had low and non-significant SMRs. Regarding other risk factors for kidney cancer, blood pressure and body mass index data were only available for one of the four kidney cancer deaths.

Although confounding is a candidate explanation for the excess urinary organ cancers, another possible explanation could be the long-term impact of excretion of fibers and/or the dissolution of fiber elements through the urinary track. Glass and ceramic fibers of exposed workers have been detected in the urine of workers (Savolainen et al., 1996). In a review by Gunter et al., asbestos fibers were found in the bladder wall, intestinal mucosa, kidneys, placenta, and other organs as well as biological fluids including sputum and urine in occupational or non-occupational exposed populations (Gunter et al., 2007).

Elevated SMRs also were observed for leukemia and lymphatic cancers in the lower but not the higher exposure group, perhaps indicating chance findings or possibly related to different etiologic agents since exposure to asbestos, and MMVFs have not been confirmed to be associated with these cancers and animal inhalation studies have not explored this potential relationship. Of the 10 leukemia deaths, five were acute myelocytic leukemia, two were chronic lymphocytic leukemia, one was acute leukemia not otherwise classified (NOC), one was myeloid leukemia NOC, and one was leukemia NOC. Two were millwrights, two were welders, and the remaining six had jobs with diverse occupational exposures. Because seven of 10 were in the lower exposure group, it seems unlikely that RCF is the causal agent.

Although the power to detect mesothelioma in this cohort is low, two cases have been identified. One was deceased and hired in 1977 with a CFE of 52.3 fiber-months/cc and RCF latency at time of death of 38 years. The other is living and hired in 1969 with primary job titles of application engineer and sales representative (with unmeasured exposures), who reported industrial furnace insulation tear out and installation activities. Though this is a mortality study, for thoroughness, we re-analyzed the whole cohort as if the living mesothelioma case was deceased; the SMR was 4.58 with a wide confidence interval (0.55, 16.55). The large confidence interval is due to the low power associated with a rare outcome, relatively small sample, and person-years at risk. The deceased pathologically unconfirmed mesothelioma case reported exposure to asbestos during 6 days of sheet metal work, a 6.5-year history as an auto mechanic changing clutch plates and brakes and use of asbestos home insulation with an estimated overall cumulative asbestos exposure of 5.75 months. Other reported jobs included machinist apprentice, overhauling railroad steam engines in the 1950s, aviation electrician from 1952 to 1956 in the Navy, and a technician in fuel systems for South Bend Bendix Aviation from the mid-1950 to 1970s, which manufactured asbestos containing friction brake products (NY Times, 2002).

The living, pathologically confirmed, mesothelioma case worked in the RCF production industry over 40 years with RCF latency of 50 years at time of diagnosis. A chest computed tomography (CT) scan documented changes consistent with bilateral calcified pleural plaques. Job positions included application engineer and sales representative. These jobs included some supervision and installation of RCF in kilns and furnaces at numerous industrial sites. During these job activities, the individual reported exposure to RCF as well as asbestos from residual asbestos contained in kiln and furnace products. A French case–control study (Lacourt et al., 2014) that utilized job exposure matrices to assess retrospective exposure estimates suggested that co-exposure to asbestos and RCF in comparison with asbestos alone may increase the risk for mesothelioma.

The primary study limitation is related to low power to detect an effect for some cancers including mesothelioma. In addition, there could be error in estimation of exposures because both historical and recent exposure data were used, causing potential exposure misclassification. However, because most of the exposure data were collected during the study and individuals have been followed over an extended time, we believe this limitation is less salient. A strength of the study is the length of latency, which is necessary for identifying cancers such as mesothelioma. The higher exposed living group now has a mean latency of 43.0 years (Table 1).

## 5 | CONCLUSIONS

This study did not demonstrate any increased lung cancer mortality in comparison with local, state, or national populations. The cause for the elevated mortality in urinary cancers is likely multifactorial including past smoking and potential past industrial exposures during the early years of RCF production. Because of the inability to discern the independent effect of RCF exposure in the presence of past asbestos exposure in both mesothelioma cases and a possible association between the RCF production process and urinary cancers, the mortality study is ongoing and deaths from all causes will be monitored.

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### CONFLICT OF INTEREST

The funding for this study from industry sources went to the University of Cincinnati. The investigators were independent researchers whose funding came from the University and declare no conflict of interest.

### FUNDING SOURCES

This work was supported by a contract from the High Temperature Insulation Wool Coalition to the University of Cincinnati College of Medicine.

### DATA AVAILABILITY STATEMENT

De-identified data from this cohort have been shared with others, resulting in several publications. All requests for data will be evaluated by Study Team leadership and the Scientific Advisory Board

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### REFERENCES

American Cancer Society. Key statistics for bladder cancer (2021). https://www.cancer.org/cancer/bladder-cancer/about/key-statistics

Cumberbatch, M. G. K., Jubber, I., Black, P., Esperto, F., Figueroa, J. D., Kamat, A. M., Kiemeney, L., Lotan, Y., Pang, K., Silverman, D. T., Znaor, A., & Catto, J. W. F. (2018). Epidemiology of bladder Cancer: A systematic review and contemporary update of risk factors in 2018. *European Urology*, *74*(6), 784–795. https://doi.org/10.1016/j.eururo.2018.09.001

Davis, J. M. G., Addison, J., Bolton, R. E., Donaldson, K., Jones, A., & Wright, A. (1984). The pathogenic effects of fibrous ceramic aluminum silicate glass administered to rats by inhalation and peritoneal injection. In: Biological effects of man-made mineral fibers. *Proceedings of a WHO/IARC Conference*, *2*. Copenhagen, Denmark: World Health Organization/International Agency for Research on Cancer, 303–322.

Filion, K. B., Steffen, L. M., Duval, S., Jacobs, D. R. Jr., Blackburn, H., & Luepker, R. V. (2012). Trends in smoking among adults from 1980 to 2009: The Minnesota heart survey. *American Journal of Public Health*, *102*(4), 70–713.

Gu, Y., He, W., Wang, Y., Chen, J., Wang, H., Gao, P., Yang, S., Zhu, X., Ma, W., & Li, T. (2020). Respiratory effects induced by occupational exposure to refractory ceramic fibers. *Journal of Applied Toxicology*, *41*, 421–441.

Gunter, M. E., Belluso, E., & Mottana, A. (2007). Amphiboles: Environmental and health concerns. *Reviews Mineral Geochemistry*, *67*(1), 453–516. https://doi.org/10.2138/rmg.2007.67.12

International Agency for Research on Cancer (IARC). (2002). IARC monographs on the evaluation of carcinogenic risks to humans: Man-made vitreous fibers (Volume *81*). Lyon, France: World Health Organization.

Lacourt, A., Rinaldo, M., Gramond, C., Ducamp, S., Gilg Soit Ilg, A., Goldberg, M., Pairon, J. C., & Brochard, P. (2014). Co-exposure to refractory ceramic fibres and asbestos and risk of pleural mesothelioma. *The European Respiratory Journal*, *44*, 725–733. https://doi.org/10.1183/09031936.00079814

LeMasters, G., Lockey, J. E., Hilbert, T. J., Levin, L. S., Burkle, J. W., Shipley, R., Perme, C., Meyer, C. A., & Rice, C. H. (2017). A 30-year mortality and respiratory morbidity study of refractory ceramic fiber workers. *Inhalation Toxicology*, *29*(10), 462–470. https://doi.org/10.1080/08958378.2017.1394931

LeMasters, G. K., Lockey, J. E., Yiin, J. H., Hilbert, T. J., Levin, L. S., & Rice, C. H. (2003). Mortality of workers occupationally exposed to refractory ceramic fibers. *Journal of Occupational and Environmental Medicine*, *45*, 440–450. https://doi.org/10.1097/01.jom.0000052968.43131.b5

Lockey, J. E., LeMasters, G. K., Levin, L., Rice, C., Yiin, J., Reutman, S., & Papes, D. (2002). A longitudinal study of chest radiographic changes of workers in the refractory ceramic fiber industry. *Chest*, *121*, 2044–2051. https://doi.org/10.1378/chest.121.6.2044

Mast, R. W., McConnell, E. E., Anderson, R., Chevalier, J., Kotin, P., Bernstein, D. M., Thevenaz, P., Glass, L. R., Miiller, W. C., & Hesterberg, T. W. (1995). Studies on the chronic toxicity (inhalation) of four types of refractory ceramic fiber in male Fischer 344 rats. *Inhalation Toxicology*, *7*, 425–467. https://doi.org/10.3109/08958379509015208

Mast, R. W., McConnell, E. E., Hesterberg, T. W., Chevalier, J., Kotin, P., Thevanaz, P., Bernstein, D. M., Glass, L. R., Miiller, W., & Anderson, R. (1995). Multiple-dose chronic inhalation toxicity study of size-separated kaolin refractory ceramic fiber in male Fischer rats. *Inhalation Toxicology*, *7*, 469–502. https://doi.org/10.3109/08958379509015209

Maxim, L. D., & Utell, M. J. (2018). Review of refractory ceramic fiber (RCF) toxicity, epidemiology and occupational exposure. *Inhalation Toxicology*, *30*(2), 49–71. https://doi.org/10.1080/08958378.2018.1448019

McConnell, E. E., Mast, R. W., Hesterberg, T. W., Chevalier, J., Kotin, P., Bernstein, D. M., Thevenaz, P., Glass, L. R., & Anderson, R. (1995). Chronic inhalation toxicity of a kaolin-based refractory ceramic fiber in

Syrian golden hamsters. *Inhalation Toxicology*, *7*, 503–532. https://doi.org/10.3109/08958379509015210

National Cancer Institute (NCI). Surveillance, epidemiology, and end results program (2021). https://seer.cancer.gov/statfacts/index.html

National Toxicology Program (NTP). (2016). *Report on carcinogens* (Fourteenth ed.). U.S. Department of Health and Human Services, Public Health Service. https://ntp.niehs.nih.gov/go/roc14

New York Times. (2002). Honeywell says asbestos verdict was more than it had disclosed. http://www.nytimes.com/2002/04/18/business/honeywell-says-asbestos-verdict-was-more-than-it-had-disclosed.html

Rice, C. H., Levin, L. S., Borton, E. K., Lockey, J. E., Hilbert, T. J., & Lemasters, G. K. (2005). Exposures to refractory ceramic fibers in manufacturing and related operations: A 10-year update. *Journal of Occupational and Environmental Hygiene*, *2*, 462–473. https://doi.org/10.1080/15459620500240659

Savolainen, H., Cosca-Sliney, R., & Guillemin, M. (1996). Detection of occupational exposure to inorganic fibres by urinary fibre anlysis. *Occup Hygiene.*, *3*, 351–357.

Scelo, G., & Larose, T. L. (2018). Epidemiology and risk factors for kidney Cancer. *Journal of Clinical Oncology.*, *36*, 3574–3581. https://doi.org/10.1200/JCO.2018.79.1905

Schubauer-Berigan, M. K., Hein, M. J., Raudabaugh, W. M., Ruder, A. M., Silver, S. R., Spaeth, S., Steenland, K., Petersen, M. R., & Waters, K. M. (2011). Update of the NIOSH life table analysis system: A person-years analysis program for the windows computing environment. *American Journal of Industrial Medicine*, *54*, 915–924. https://doi.org/10.1002/ajim.20999

Smith, D. M., Ortiz, L. W., Archuleta, R. F., & Johnson, N. F. (1987). Long-term health effects in hamsters and rats exposed chronically to man-made vitreous fibres. *The Annals of Occupational Hygiene*, *31*(4B), 731–754.

Suder Egnot, N., Benson, S. M., Vater, M. F., Hazan, R., Patel, O., & Marsh, G. M. (2020). Systematic review and meta-analysis of epidemiological literature evaluating the association between exposure to man-made vitreous fibers and respiratory tract cancers. *Regulatory Toxicology and Pharmacology*, *112*, 104585.

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# Refractory ceramic fibers: Fiber characteristics, potential health effects and clinical observations

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A B S T R A C T

Refractory ceramic fibers (RCFs) are amorphous fibers that belong to a class of materials termed synthetic vitreous fibers (SVFs), also called man-made mineral fibers (MMMFs), which includes alkaline earth silicate wool, glass wool, rock (stone) wool, slag wool, and special-purpose glass fibers. RCFs are more durable and biopersistent than several other SVFs, although very much less biopersistent than either amosite or crocidolite asbestos. Chronic inhalation studies indicated that rats and hamsters exposed to RCF fibers developed fibrosis and tumors. Epidemiological studies at the University of Cincinnati funded by the Industry indicated that exposed workers; (1) exhibited symptoms (e.g., dyspnea) similar to those reported in other dust-exposed populations, (2) developed statistically, but not clinically, significant deficits in certain measures of pulmonary function in a cross sectional study, but no excessive decline in a longitudinal study, and (3) a dose related increase in pleural plaques, but no interstitial fibrosis. The 2003 mortality study indicated no incremental lung cancer and no cases of mesothelioma. RCF producers developed a comprehensive industry wide product stewardship program (PSP) beginning in the late 1980s. In conjunction with the PSP, there has been a progressive decrease in the TWA concentration of fibers by manufacturers and end-users. The research program has successfully produced more soluble fibers and undertaken efforts to develop larger diameter fibers. The results of the ongoing epidemiology studies confirm that occupational exposure to RCF is associated with the development of pleural plaques and minor decrements in lung function, but no interstitial fibrosis or incremental lung cancer.

## 1. Introduction

RCFs (CAS no. 142844-00-6), first invented in the 1940s, are amorphous fibers that belong to a class of materials termed synthetic vitreous fibers (SVFs), also called synthetic mineral fibers (SMFs), man-made mineral fibers (MMMFs), or man-made vitreous fibers (MMVFs), which also includes alkaline earth silicate (AES) wool, glass wool, rock (stone) wool, slag wool, and special-purpose glass fibers (Utell and Maxim, 2010). RCFs are produced by melting (at ~1925 °C) a mixture of alumina ($Al_2O_3$) and silica ($SiO_2$) in approximately equal proportions. Other inorganic oxides, such as $Zr_2O_3$, $Cr_2O_3$, $B_2O_3$, and $TiO_2$ are sometimes added to alter the properties (e.g., durability or maximum end use temperature) of the resulting product. RCFs can also be made by melting blends of calcined kaolin, alumina, and silica. The molten material is made into fibers by either a blowing or a spinning process. RCFs are produced in a variety of physical forms, including bulk fiber, blanket, modules (compressed blanket with hardware attached for easy installation), felt, paper, and vacuum formed shapes.

### 1.1. Physical properties and implications

As produced or processed some RCFs are respirable (Greim et al., 2014; Maxim et al., 2008 and contained references). In terms of dimensions, RCFs can be elongate particles (Middendorf et al., 2007; National Research Council, 2010)—though not necessarily Elongate Mineral Particles (EMPs) as this term is generally understood, since RCFs are vitreous, rather than crystalline, and do not contain any type of asbestos.

RCFs have several desirable physical properties as high temperature insulating materials. These include low thermal conductivity, low heat storage (low volumetric heat capacity), high thermal shock resistance, light weight, good corrosion resistance, and ease of installation (ERM, 1995). Depending upon the formulation, the maximum use temperature can be as high as 1430 °C (ERM, 1995; NIOSH, 2006; TIMA, 1993). For this reason, RCFs (and certain other fibers) are also termed high-temperature insulating wools (HTIWs). The combination of low thermal conductivity, lightweight, and low heat storage make RCF useful as a lightweight high-temperature insulation material. Because of these

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properties, RCF applications are principally industrial, where it is used as a furnace lining in the chemical, fertilizer, petrochemical, steel, glass, ceramic, cement, foundry, and forging industries (Mast et al., 2000; Utell and Maxim, 2010).

Turning now to physical properties relevant to potential fiber toxicity, most scientists subscribe to the so-called 3Ds (dose-durability-dimension) theory of fiber toxicity (see e.g., NIOSH, 2006). The importance of dose is obvious—ceteris paribus, lower cumulative exposure doses are likely to result in a lower response.

Fiber dimensions (diameter and length) are relevant for two reasons:

- Fiber *diameters* are relevant because diameters affect the respirability of fibers. Broadly, fibers with diameters > 3 μm (μm) do not penetrate the branching airway to reach the distal pulmonary/alveolar region. What is relevant here is the distribution of fiber diameters as found in or near the breathing zone of those exposed, not the diameters of the bulk fibers.
- Fiber *lengths* are potentially relevant because there is evidence that longer fibers (at least those longer than approximately 20 μm) are potentially more toxic because these are too large to be fully engulfed by macrophages.

The ability of the fiber to remain in the lung, termed *durability* if measured in in-vitro studies, or biopersistence if measured in in vivo studies has also been found to be a key determinant of fiber toxicity (Bernstein et al., 2001a, 2001b; Eastes and Hadley, 1994; Eastes et al., 1996; Greim et al., 2014; Hesterberg et al., 1994, 1998a; ILSI Working Group, 2005; McConnell, 2000; Maxim et al., 2006). Fibers that remain in the lung longer have a greater potential to cause adverse health effects. Durability/biopersistence can be measured in-vitro by a parameter termed $K_{dis}$ and in vivo as a weighted half time $WT_{1/2}$ measured in either inhalation or intra tracheal measurements. There is good correlation between these two metrics (Maxim et al., 2006). Fig. 1 shows weighted half-times (days) of long (> 20 μm) fibers from short-term inhalation studies for two types of amphibole asbestos (crocidolite and amosite) and several SVFs (including RCF) as measured by Hesterberg et al. (1998a). As can be seen, RCFs are more durable and biopersistent than several other SVFs, although very much less biopersistent than either amosite or crocidolite asbestos (see data from various sources summarized in Brown et al., 2005; Greim et al., 2014; Matsuzaki et al., 2015; Maxim et al., 2006). Based on these data the potential toxicity of RCF would be expected to be more toxic than glass wool, comparable to rockwool, and very much less toxic than amphibole asbestos—a in vitro conjecture supported by available epidemiological data.

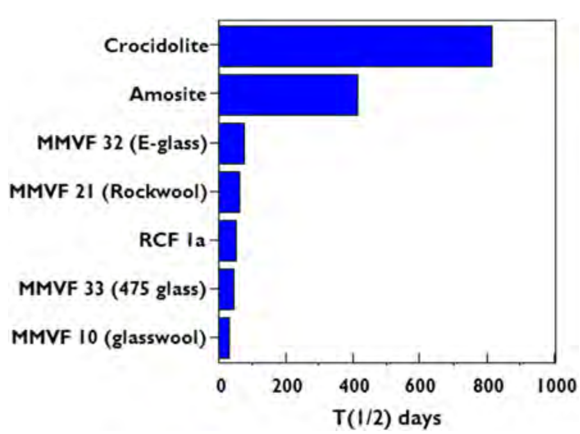


**Fig. 1.** Biopersistence data shown as weighted half-times for Crocidolite asbestos, Amosite asbestos, MMVF 21 (rockwool), MMVF 32 (E glass), RCF, MMVF 33 (special application glass wool), MMVF 10 (glasswool), and MMVF 22 (slagwool) (Greim et al., 2014; Hesterberg et al., 1998a; Maxim et al., 2006). Measured values of weighted half-times, the most relevant measure of biopersistence, range from just a few days for very low biopersistent fibers, such as certain glass wools, to 1000 or more days for some forms of amphibole asbestos.

Fibers in the lung are removed by three mechanisms (see e.g., Maxim et al., 2006), removal of short fibers by macrophages, dissolution of fibers, and breakage of fibers. The breakage mechanism is also a relevant fiber property. Some fibers, such as chrysotile asbestos break along the longitudinal axis, thus increasing the number of long, thin fibers. Others, such as RCF and other SVFs, undergo transverse breakage, resulting in shorter fibers that are more easily removed by macrophages.

As noted above, studies of laboratory animals exposed to RCF by various routes have resulted in fibrosis and tumors and IARC placed RCF in Group 2B (possibly carcinogenic to humans) on the basis of sufficient evidence in experimental animals and inadequate evidence in humans.

The Scientific Committee on Occupational Exposure Limits (SCOEL, 2011) classified refractory ceramic fibers as a secondary genotoxic carcinogen and supported a practical threshold. Inflammation was considered the predominant manifestation of RCF toxicity. However, the animal data are not easily interpreted in terms of possible risk implications for humans as the key inhalation study resulted in overload (see e.g., Brown et al., 2005; Maxim et al., 2003).

### 1.2. Product stewardship program

The earliest toxicology studies indicated that RCF was no more toxic than what was termed a nuisance dust. But later animal studies, using more advanced protocols (e.g. nose-only inhalation) resulted in fibrosis and tumors. On the basis of the later animal study results, RCF producers decided to develop a comprehensive industry wide product stewardship program (PSP) beginning in the late 1980s (Maxim et al., 2008; Utell and Maxim, 2010). Table 1 provides a high-level overview of the eight major components (exposure monitoring, medical monitoring, development of improved workplace controls/practices, specification of respirator required jobs and other elements of a respiratory protection program, worker training, product research, environmental responsibility, and the development of an efficient communication strategy) included in this multi-faceted stewardship program. The program was conducted originally (1993–1998) under the oversight of the U.S. Environmental Protection Agency (EPA) and later under the oversight of the Occupational Safety and Health Administration (OSHA). Developed originally under the sponsorship of the Refractory Ceramic Fibers Coalition (RCFC) and later under the successor organization, the High Temperature Insulation Wools (HTIW) Coalition, this program continues today.

This paper focuses on three aspects of the PSP; exposure monitoring and controls, epidemiological morbidity studies, and product research. The program also includes an ongoing mortality study (see LeMasters et al., 1998, 2003 for earlier results), which is omitted here pending completion of the analysis of data from the latest update.

### 1.3. Exposure monitoring and control

Exposure monitoring is conducted at both HTIW Coalition member plants and customer facilities using a statistically designed stratified random sampling plan (SRSP). Time weighted average (TWA) fiber concentrations are measured on workers doing various jobs on various forms of RCF. The SRSP is designed to provide accurate estimates of weighted average fiber concentrations for a fixed total sample size. The purposes of exposure monitoring are to:

**Table 1**
Major components and elements/features of the industry Product Stewardship Program. The exposure monitoring features focus on presenting objective data on occupational exposure (with and without correction for the protective effect of respirators) to RCFs in production sites and customer facilities. Workplace controls/practices include use of exposure monitoring and other data collected to identify efficient engineering controls and workplace practices. Environmental responsibility is a catch-all category used to denote efforts to minimize consumption of raw materials, conserve energy, and minimize waste generation rates by increasing process yields, recycling, and other means.

| Component | Elements/features |
|---|---|
| Exposure monitoring at HTIW Coalition and customer facilities | Verify compliance with recommended exposure guideline (REG)<br>Assess determinants of exposure<br>Track trends<br>Benchmarking |
| Medical monitoring/health effects research/ epidemiology studies | Continuing medical surveillance of current workers<br>Continuing mortality study of present and former workers |
| Workplace controls/practices | Search for improved engineering controls and workplace practices to reduce occupational exposure |
| Respirator use | Ensure appropriate respirators used when necessary |
| Training | Provide training sessions for employees of HTIW producers, customers, and others |
| Product research | Encourage research to develop improved understanding of determinants of fiber toxicity and the development of less biopersistent alternatives to RCF capable of substituting for RCF in various applications. |
| Environmental responsibility | Minimize consumption of natural resources, reduce waste generation, and conserve energy. |
| Communications | Disseminate PSP results to key stakeholders<br>Provide Annual Reports to OSHA |

- Verify compliance with the program's recommended exposure guideline (REG) of 0.5 fibers per cubic centimeter[1] (0.5 f/cm$^3$ or 0.5 f/ml) for RCF, or other applicable occupational exposure limits (OELs),
- Present objective data on occupational exposure (with and without correction for the protective effect of respirators) to RCFs,
- Measure time trends in worker exposure,
- Provide relevant data for benchmarking, and to
- Learn more about the determinants of exposure.

To date the exposure database includes nearly 26,000 personal monitoring observations (time weighted average fiber concentration measurements) collected in the United States and Europe. Customers to be monitored include both those selected at random ("selectees") and those who specifically request monitoring ("volunteers").[2] A typical monitoring visit entails a "walk around" observation, worker training, exposure monitoring, and an exit interview. Monitoring results and any recommendations are included in a visit report provided to the customer by the HTIW Coalition member collecting the monitoring data. Fig. 2 highlights the results of the exposure control efforts by showing the weighted average fiber concentrations (fibers per milliliter) measured over the period from 1990 through 2016. Weights used in computing the weighted average fiber concentration are equal to the proportion of workers in each of eight functional job categories [FJCs]. Respirators are used for certain difficult to control jobs, but the concentrations shown in Fig.2 do not take into account the protective effect of respirator use.

As can be seen, fiber concentrations at both customer facilities and manufacturer plants have decreased substantially over the years and (with the exception of 1990 for customers) have been well beneath the industry's recommended exposure guideline (REG). Perhaps more important, weighted average fiber concentrations at customer facilities (originally higher than those at manufacturing facilities) have decreased even more than those at manufacturers as technical knowledge about ways to reduce exposures, including installation of engineering controls and implementation of improved workplace practices, has been exploited by customers.

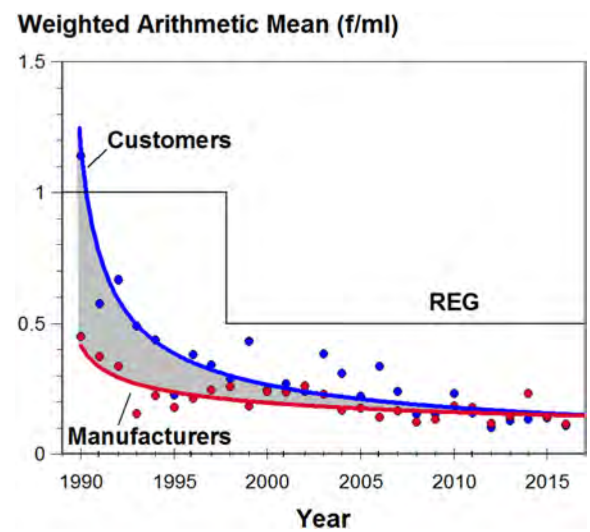


**Fig. 2.** Time trends in weighted average TWA concentrations at manufacturer and customer facilities. *The gap between exposures at customer and manufacturer facilities (shown by the shaded area) has decreased over time to the point that weighted average exposures are nearly the same for both groups.*

### *1.4. Morbidity studies*

Data from the latest update to the ongoing mortality (as well as morbidity) have recently been published. The RCF industry has sponsored several epidemiological studies on workers exposed to these fibers. The studies evaluated/measured symptoms, X-rays, pulmonary function, and mortality. Collectively, these studies indicated that exposed workers (1) exhibited symptoms (e.g., dyspnea) similar to those reported in other dust-exposed populations, (2) developed statistically significant, but not clinically significant, deficits in certain measures of pulmonary function in a cross-sectional study, but no excessive decline in a later longitudinal study (McKay et al., 2011), and (3) experienced a dose-related increase in pleural plaques, but no interstitial fibrosis. In the most recent RCF morbidity study, Lemasters et al. (2017) at the University of Cincinnati reported results of x-ray findings in 1451 RCF workers. Chest radiographs were administered every three years from 5 facilities. The chest films were interpreted independently by three Board certified radiologists who were B-readers using the standard ILO 1980 International Classification of Radiographs for pneumoconiosis. The radiological investigation of workers in the US cohort exposed to

[1] This REG was established on the basis of prudence and demonstrated feasibility, not on any demonstrated risk. Occupational exposure limits (OELs) have been established in many countries of the world and vary from 0.1 to 2.0 f/ml (Harrison et al., 2015). This REG is numerically identical with the recommended exposure limit (REL) published by NIOSH (NIOSH, 2006).

[2] Studies show that the average fiber concentrations among volunteers do not differ significantly from selectees.

RCF revealed a statistically significant increase in the prevalence of pleural plaques. The overall rate of pleural changes reported by Lemasters et al. (2017) in their most recent publication was 6.1% ($n = 89$), which increased across exposure categories reaching, in the highest cumulative exposure category, 21.4% (adjusted odds ratio (aOR). 6.9, 95% CI 3.6–13.4) and 13.0% (OR. 9.1, 95% CI 2.5–33.6) for all subjects and for those with no potential asbestos exposure, respectively. This compared to an earlier report were pleural changes were seen in 27 workers (2.7%) (Lockey et al., 2002*)* The increase in pleural plaques with time is not surprising as the presence of plaques is likely to be related to increasing latency. Prevalence among recent hires (after 1985) was similar to the background. Interstitial changes were not elevated.

To place the incidence of pleural plaques found in the RCF-exposed cohort into perspective, it is useful to compare this to other cohorts. The US Mine Safety and Health Administration (MSHA) [Federal Register, 2005] claims that the prevalence of pleural plaques ranges from 0.53% to 8% in environmentally exposed populations. Furthermore, the average prevalence of pleural abnormalities in populations with environmental exposure in areas of known asbestos/related mineralogy ranges from 1.1 to 60.3%, and the average prevalence of pleural abnormalities in populations with known occupational exposure to asbestos ranges from 1.3 to 72.6% (Utell and Maxim, 2010).

The available evidence is consistent with the hypothesis that the development of pleural plaques is a marker of exposure to several fibers, particularly asbestos. Absent other nonmalignant pleural disease, pleural plaques are not associated with respiratory symptoms or (in most individuals) clinically significant impairments to lung function (Maxim et al., 2015). In cohorts occupationally exposed to asbestos there is a correlation between the presence of pleural plaques and malignant effects (lung cancer and mesothelioma), but the evidence indicates that this relationship is a consequence of the degree of exposure to asbestos and that the presence of pleural plaques does not, of itself, independently affect risk levels. The studies of Pairon et al. (2013) and colleagues suggest that plaques might be an independent risk factor and further research on this topic is appropriate, but these results cannot be regarded as definitive.

In contrast to the pleural changes, the prevalence of parenchymal abnormalities did not differ from workers exposed to other types of dust (Lockey et al., 1996, 2002). There was no increase in interstitial lung disease or pulmonary fibrosis.

The 2003 mortality study indicated that there was no incremental lung cancer and no cases of mesothelioma. (The mortality study indicated that there was a statistically significant association with cancers of the urinary organs, an unexpected finding, which may be due to chance). The mortality study is being updated.

### *1.5. Product research*

Another key component of the industry PSP is the search for and development of new, less biopersistent fibers, capable of substituting for RCF in certain high temperature applications. These efforts have been successful and led to the development of a new class of high temperature insulating wools termed alkaline earth silicate (AES) wools. AES wools became commercially available during the 1990s. Typical AES compositions are $SiO_2$ (50–82%), CaO and MgO (18–43%), and minor amounts of $Al_2O_3$ and other oxides. Fibers with lower alumina compositions have significantly lower durability/biopersistence. AES wool fiber diameters are similar to those for RCF and, in consequence, airborne fiber concentrations (also measured as part of the industry PSP) for comparable FJCs are also quite similar.

Biopersistence and other studies (see e.g., Brown et al., 2002; Brown and Harrison, 2012; Campopiano et al., 2014; Cavallo et al., 2015; Harrison and Brown, 2011; Hesterberg et al., 1998b; Maxim et al., 1999; Ohsawa, 2005; Ziemann et al., 2014) have shown AES wool fibers to have significantly lower biopersistence than RCFs and minimal toxicology in subchronic studies. Hesterberg et al., 1998b performed a chronic (2 year) nose-only inhalation study that indicated that one AES wool (×607) was neither fibrogenic nor carcinogenic.

AES wools are not classified as carcinogens by any regulatory or advisory body. AES wools are capable of substituting for RCF for certain, but not all, industrial applications. Depending upon composition, AES wools can be used at temperatures up to 2300° F (1200 °C) though most are used at temperatures < 900 °C.

## 2. Conclusions

The evaluation of the impact of occupational RCF exposure on human health is a long-term process that attempts to reconcile animal experimental data with the results of the human epidemiologic studies. Results of animal inhalation studies showed that exposure to high concentrations of RCF can cause fibrosis and tumors, although interpretation of these tests has been complicated by probable particle overload. Results of ongoing epidemiological studies demonstrate that exposure to RCF causes selected respiratory symptoms and pleural plaques. However, these ongoing epidemiological studies of occupationally exposed cohorts have thus far failed to demonstrate progressive decrements in lung function, interstitial fibrosis, excess lung cancer, or mesothelioma. The mortality study has not shown any increase in death rate (all deaths), cancer deaths, or respiratory deaths. A statistically significant increase in cancers of the urinary organs was found; but the biological significance of this finding is uncertain. The PSP has proven successful in reducing fiber concentrations and continues to develop less biopersistent fibers. An update of the morbidity and mortality study from the University of Cincinnati has recently been published (Lemasters et al., 2017) and confirmed that occupational exposure to RCF is associated with the development of pleural plaques, but no interstitial fibrosis or incremental lung cancer. One reported, but unconfirmed, mesothelioma was found in an individual with prior occupational asbestos exposure. Evidence supporting a finding that urinary tumors are associated with RCF exposure remains, but is weaker (Maxim and Utell, 2018). Product stewardship efforts have been successful in substantially reducing occupational exposures to RCF and may well be responsible for the virtual absence of pleural plaques in workers hired after the introduction of the PSP as well as the absence of a progressive loss of lung function in the longitudinal study of pulmonary function.

## Conflict of interest

The authors received no financial support for preparation of this manuscript. Mark Utell serves as the consulting medical director of Unifrax, a major manufacturer of refractory ceramic fibers. He has also served as a consultant to Unifrax and the High Temperature Insulation Wool (HTIW) Coalition. L. Daniel Maxim serves as a consultant to several firms in the mineral industry, including those that produce refractory ceramic fibers. Maxim is the Chair of the Ceramic Fiber Advisory Board for Unifrax, a group of independent experts in fiber technology, toxicology, epidemiology and related fields.

## References

Bernstein, D.M., Sintes, J.M.R., Ersboell, B.K., Kunert, J., 2001a. Biopersistence of synthetic mineral fibers as a predictor of chronic inhalation toxicity in rats. Inhal. Toxicol. 13, 823–849.
Bernstein, D.M., Sintes, J.M.R., Ersboell, B.K., Kunert, J., 2001b. Biopersistence of synthetic mineral fibers as a predictor of chronic intraperitoneal injection tumor response in rats. Inhal. Toxicol. 13, 851–875.
Brown, R.C., Harrison, P.T., 2012. Alkaline earth silicate wools–A new generation of high temperature insulation. Regul. Toxicol. Pharmacol. 64 (2), 296–304.
Brown, R.C., Bellmann, B., Muhle, H., Ernst, H., Pohlmann, G., Sebastien, P., 2002. Subchronic studies on man-made vitreous fibres: toxicity results. Ann. Occup. Hyg. 46 (Suppl. 1), 102–104.
Brown, R.C., Bellmann, B., Muhle, H., Davis, J.M.G., Maxim, L.D., 2005. Survey of the

biological effects of refractory ceramic fibres: overload and its possible consequences. Ann. Occup. Hyg. 49, 295–307.

Campopiano, A., Cannizzaro, A., Angelosanto, F., Astolfi, M.L., Ramires, D., Olori, A., Canepari, S., Iavicoli, S., 2014. Dissolution of glass wool, rock wool and alkaline earth silicate wool: morphological and chemical changes in fibers. Regul. Toxicol. Pharmacol. 70 (1), 393–406.

Cavallo, D., Ursini, C.L., Fresegna, A.M., Ciervo, A., Maiello, R., Tassone, P., Iavicoli, S., Cannizzaro, A., Angelosanto, F., Campopiano, A., 2015. Study of cytotoxic and inflammatory effects of alkaline earth silicate and polycrystalline wools in human bronchial epithelial cells. Toxicology Letters 2 (238) (p.S312).

Eastes, W., Hadley, J.G., 1994. Role of fiber dissolution in biological activity in rats. Reg. Toxicol. Pharm. 20, S104–S112.

Eastes, W., Hadley, J.G., Bender, J.R., 1996. Assessing the biological activity of fibers: insights into the role of fiber durability. J. Occup. Health Safety Aust NZ 12, 381–385.

Environmental Resources Management (ERM), 1995. Description and characterization of the ceramic fibres industry of the European Union. ERM Is a Trading Name of ERL. Environmental Resources Limited, Brussels, Belgium.

Federal Register, 2005. Part II, Department of Labor, Mine Safety and Health Administration, 30 CFR Parts 56, 57, and 71, Asbestos Exposure Limit; Proposed Rule. Vol. 70. pp. 43950–43989 (No. 145 Friday, July 29).

Greim, H., Utell, M.J., Maxim, L.D., Niebo, R., 2014. Perspectives on refractory ceramic fiber (RCF) carcinogenicity: comparisons with other fibers. Inhal. Toxicol. 26 (13), 789–810.

Harrison, P.T., Brown, R.C., 2011. Devitrification of artificial fibres. Ann. Occup. Hyg. 55 (7), 823–824.

Harrison, P., Holmes, P., Bevan, R., Kamps, K., Levy, L., Greim, H., 2015. Regulatory risk assessment approaches for synthetic mineral fibres. Reg. Toxicol. Pharm. *73* (1), 425–441.

Hesterberg, T.W., Miiller, W.C., Mast, R., et al., 1994. Relationship between lung biopersistence and biological effects of man-made vitreous fibers after chronic inhalation in rats. Environ. Health Perspect. 102, 133–137.

Hesterberg, T.W., Chase, G., Axten, C., et al., 1998a. Biopersistence of synthetic vitreous fibers and amosite asbestos in the rat lung following inhalation. Toxicol. Appl. Pharmacol. 151, 262–275.

Hesterberg, T.W., Hart, G.A., Chevalier, J., Miiller, W.C., Hamilton, R.D., Bauer, J., Thevenaz, P., 1998b. The importance of fiber biopersistence and lung dose in determining the chronic inhalation effects of X607, RCF1, and chrysotile asbestos in rats. Toxicol. Appl. Pharmacol. 153 (1), 68–82.

ILSI Working Group, 2005. Testing of fibrous particles: short-term assays and strategies. lnhal. Toxicol. 17, 497–537.

Lemasters, G.K., Lockey, J.E., Levin, L.S., McKay, R.T., Rice, C.H., Horvath, E.P., Papes, D.M., Lu, J.W., Feldman, J.H., 1998. An industry-wide pulmonary study of men and women manufacturing refractory ceramic fibers. Am. J. Epidemiol. 148, 910–919.

Lemasters, G.K., Lockey, J.E., Yiin, J.H., Hilbert, T.J., Levin, L.S., Rice, C.H., 2003. Mortality of workers occupationally exposed to refractory ceramic fibers. J. Occup. Environ. Med. 45, 440–450.

Lemasters, G., Lockey, J.E., Hilbert, T.J., Levin, L.S., Burkle, J.W., Shipley, R., Perme, C., Meyer, C.A., Rice, C.A., 2017. A thirty year mortality and respiratory morbidity study of refractory ceramic Fiber workers. Inhal. Toxicol. 29, 462–470.

Lockey, J., Lemasters, G., Rice, C., Hansen, K., Levin, L., Shipley, R., Spitz, H., Wiot, J., 1996. Refractory ceramic fiber exposure and pleural plaques. Am. J. Respir. Crit. Care Med. 154, 1405–1410.

Lockey, J.E., Lemasters, G.K., Levin, L., Rice, C., Yiin, J., Reutman, S., Papes, D., 2002. A longitudinal study of chest radiographic changes of workers in the refractory ceramic fiber industry. Chest 121, 2044–2051.

Mast, R.W., Maxim, L.D., Utell, M.J., Walker, A.M., 2000. Refractory ceramic fiber: toxicology, epidemiology, and risk analyses—a review. Inhal. Toxicol. 12, 359–399.

Matsuzaki, H., Lee, S., Kumagai-Takei, N., Yoshitome, K., Yamamoto, S., Hatayama, T., Nishimura, Y., Otsuki, T., 2015. Biological effects of refractory ceramic fiber. Kawasaki Med. J. 41 (2), 57–63.

Maxim, L.D., Utell, M.J., 2018. Refractory ceramic fibers: Fiber characteristics, potential health effects and clinical observations. Toxicol. Appl. Pharmacol. 30 (2), 49–71.

Maxim, L.D., Mast, R.W., Utell, M.J., Yu, C.P., Boymel, P.M., Zoitos, B.K., Cason, J.E., 1999. Hazard assessment and risk analysis of two new synthetic vitreous fibers. Regul. Tox. Pharm. 30 (1), 54–74.

Maxim, L.D., Yu, C.P., Oberdörster, G., Utell, M.J., 2003. Quantitative risk analyses for RCF: survey and synthesis. Regul. Toxicol. Pharmacol. 38, 400–416.

Maxim, L.D., Hadley, J.G., Potter, R.M., Niebo, R., 2006. The role of fiber durability/biopersistence of silica-based synthetic vitreous fibers and their influence on toxicology. Regul. Toxicol. Pharmacol. 46, 42–62.

Maxim, L.D., Allshouse, J., Fairfax, R.F., Lentz, T.J., Venturin, D., Walters, T.E., 2008. Workplace monitoring of occupational exposure to refractory ceramic fiber - a 17-year retrospective. Inhal. Toxicol. 20, 289–309.

Maxim, L.D., Niebo, R., Utell, M.J., 2015. Are pleural plaques an appropriate endpoint for risk analyses? Inhal. Toxicol. 27, 321–334.

McConnell, E.E., 2000. A science-based paradigm for the classification of synthetic vitreous fibers. Regul. Toxicol. Pharmacol. 32, 14–21.

McKay, R.T., Lemasters, G.K., Hilbert, T.J., Levin, L.S., Tice, C.H., Borton, E.K., Lockey, J.E., 2011. A long term study of pulmonary function among U.S. refractory ceramic Fiber workers. Occup. Environ. Med. 68 (2), 89–95.

Middendorf, P., Zumwalde, R., Castellan, R., 2007. Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research. National Institute for Occupational Safety and Health. NIOSH Mineral Fibers Working Group, Washington, DC.

National Institute for Occupational Safety and Health (NIOSH), 2006. Criteria for a Recommended Standard Occupational Exposure to Refractory Ceramic Fibers. Department of Health and Human Services, Centers for Disease Control Prevention, National Institute for Occupational Safety and Health, Atlanta, GA (204pp).

National Research Council, 2010. A Review of the NIOSH Roadmap for Research on Asbestos Fibers and Other Elongate Mineral Particles. National Academies Press.

Ohsawa, M., 2005. The effect of heating on the dissolution of alkaline earth silicate fibers in a simple amino acid solution and water. Ind. Health 43 (1), 213–220.

Pairon, J.C., Laurent, F., Rinaldo, M., Clin, B., Andujar, P., Ameille, J., Brochard, P., Chammings, S., Ferretti, G., Galateau-Salle, F., Gislard, A., Letourneux, M., Luc, A., Schorl, E., Paris, C., 2013. Pleural plaques and the risk of pleural mesothelioma. J. Natl. Cancer Inst. 105, 293–301.

Scientific Committee on Occupational Exposure Limits (SCOEL), 2011. Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic fibres. SCOEL/SUM/165(September 2011) (21 p).

Thermal Insulation Manufacturers Association (TIMA) Nomenclature Committee, 1993. Man-Made Vitreous Fibers: Nomenclature, Chemical and Physical Properties. Refractory Ceramic Fibers Coalition (RCFC), Washington, DC (72 pp).

Utell, M.J., Maxim, L.D., 2010. Refractory ceramic fiber (RCF) toxicity and epidemiology: a review. Inhal. Toxicol. 22 (6), 500–521.

Ziemann, C., Harrison, P.T., Bellmann, B., Brown, R.C., Zoitos, B.K., Class, P., 2014. Lack of marked cyto-and genotoxicity of cristobalite in devitrified (heated) alkaline earth silicate wools in short-term assays with cultured primary rat alveolar macrophages. Inhal. Toxicol. 26 (2), 113–127.


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REVIEW ARTICLE

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# Review of refractory ceramic fiber (RCF) toxicity, epidemiology and occupational exposure

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**ABSTRACT**

This literature review on refractory ceramic fibers (RCF) summarizes relevant information on manufacturing, processing, applications, occupational exposure, toxicology and epidemiology studies. Rodent toxicology studies conducted in the 1980s showed that RCF caused fibrosis, lung cancer and mesothelioma. Interpretation of these studies was difficult for various reasons (e.g. overload in chronic inhalation bioassays), but spurred the development of a comprehensive product stewardship program under EPA and later OSHA oversight. Epidemiology studies (both morbidity and mortality) were undertaken to learn more about possible health effects resulting from occupational exposure. No chronic animal bioassay studies on RCF have been conducted since the 1980s. The results of the ongoing epidemiology studies confirm that occupational exposure to RCF is associated with the development of pleural plaques and minor decrements in lung function, but no interstitial fibrosis or incremental lung cancer. Evidence supporting a finding that urinary tumors are associated with RCF exposure remains, but is weaker. One reported, but unconfirmed, mesothelioma was found in an individual with prior occupational asbestos exposure. An elevated SMR for leukemia was found, but was absent in the highly exposed group and has not been observed in studies of other mineral fibers. The industry will continue the product stewardship program including the mortality study.

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## Introduction

The most recent comprehensive review of refractory ceramic fibers (RCF) toxicology, epidemiology and exposure was published in this journal in 2010 (Utell & Maxim, 2010). Although no new chronic animal bioassays were conducted since the earlier publication, there are more recent data on occupational exposures and updates from the ongoing University of Cincinnati (UC) and other epidemiology studies that are noteworthy. Additionally, several other studies have been published that are relevant to assessing possible health risks of occupational exposure to RCF.

Hoffmann et al. (2017) suggests that the procedure for selection of papers to be included in a review article be made explicit. The papers and reports included in this article were identified based on the specific knowledge of the authors (useful for reports) and a sequence of Internet searches using PubMed and Google Scholar. For papers dealing specifically with refractory ceramic fiber, search terms included; ceramic fiber, synthetic vitreous fiber, man-made mineral fiber, Alumino Silicate wool, health effects, pleural plaques, spirometry, epidemiology, toxicology, lung cancer, mesothelioma, exposure, recommended exposure guideline, recommended exposure limit, occupational exposure limit, durability, dissolution rates, biopersistence and product stewardship. The focus of this article is on developments since 2010, but earlier years were included in the searches to discover any articles that might have been missed in the 2010 review.

## Brief background

### Composition and manufacture

RCF (CAS no. 142844-00-6), first invented in the 1940s, are amorphous fibers that belong to a class of materials termed synthetic vitreous fibers (SVFs), also called synthetic mineral fibers (SMFs), man-made mineral fibers (MMMFs) or man-made vitreous fibers (MMVFs), which also includes alkaline earth silicate (AES) wool, glass wool, rock (stone) wool, slag wool and special-purpose glass fibers. RCF are produced by melting (at ∼1925 °C) a mixture of alumina ($Al_2O_3$) and silica ($SiO_2$) in approximately equal proportions. Other inorganic oxides, such as $Zr_2O_3$, $Cr_2O_3$, $B_2O_3$ and $TiO_2$ are sometimes added to alter the properties (e.g. durability or maximum end-use temperature) of the resulting product (AFSSET, 2007; NIOSH, 2006). RCF can also be made by melting blends of calcined kaolin, alumina and silica. The molten material is made into fibers by either a blowing or a spinning process. Typical compositions of RCF and other SVFs are given in several sources (AFSSET, 2007; ATSDR, 2004; IARC, 2002; National Research Council, 2000; NIOSH, 2006). As manufactured, RCF are in the form of bulk fibers.

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Subsequent processing steps are used to convert the RCF into other physical forms such as a blanket, modules (folded blanket with hardware for rapid installation), paper, felt, board, vacuum formed shapes, textiles and as a putty or paste.

### Physical properties

RCF have several desirable physical properties as a high-temperature insulating material. These include low thermal conductivity, low heat storage (low volumetric heat capacity), high thermal shock resistance, lightweight, good corrosion resistance and ease of installation (ERM, 1995). Depending upon the formulation, the maximum use temperature can be as high as 1430 °C (ERM, 1995; NIOSH, 2006; TIMA, 1993). For this reason, RCF (and certain other fibers) are also termed high-temperature insulating wools (HTIWs). These properties make RCF useful as a lightweight high-temperature insulation material.

RCF applications are principally industrial, where it is used as a furnace lining in the chemical, fertilizer, petrochemical, steel, glass, ceramic, cement, foundry, and forging industries (Mast et al., 2000a,b; Utell & Maxim, 2010). RCF is also used as fire protection for buildings and industrial process equipment, as aircraft/aerospace heat shields, and in automotive uses, such as catalytic converters, metal reinforcements, heat shields, brake pads, and airbags (Everest Consulting Associates, 1996; ERM, 1995 [focus on European applications]; Maxim et al., 1997). IARC (2002) noted that RCF production was approximately 1–2% of all mineral fibers as of that date.

Our current understanding of fiber toxicology (the so-called 3D paradigm of dose, dimension and durability; see Bernstein, 2007; Greim et al., 2014; Hesterberg & Hart 2001; Lippmann, 2014) indicates that fibers with greatest toxicological potential are those that are:

- Respirable, that has lengths $l > 5\,\mu m$, diameters $d \leq 3\,\mu m$ and aspect ratios $l/d \geq 3$ (WHO) or $\geq 5$ (NIOSH 7400 B),
- Sufficiently long (>20 µm) to impede clearance by alveolar macrophages and
- Biopersistent (not rapidly cleared from the lung by dissolution or breakage).

Refer Greim et al. (2014), Mast et al. (2000a,b) and Maxim et al. (2000) for length-diameter distributions of RCF in occupational exposures.

Figure 1 shows weighted half-times (days) of long (>20 µm) fibers from short-term inhalation studies for two types of amphibole asbestos (crocidolite and amosite) and several SVFs (including RCF) as measured by Hesterberg et al. (1998). RCF 1, one of three most common forms in the US and one of the fibers tested in the animal bioassays, was specially prepared to be rat respirable. However, later analysis (Maxim et al., 1997) showed that the particle to fiber ratio of RCF 1 was not representative of that found in workplace samples. RCF 1a was prepared from RCF 1 to match the particle to fiber ratio found in workplace samples. Additional information on RCF 1a has been published

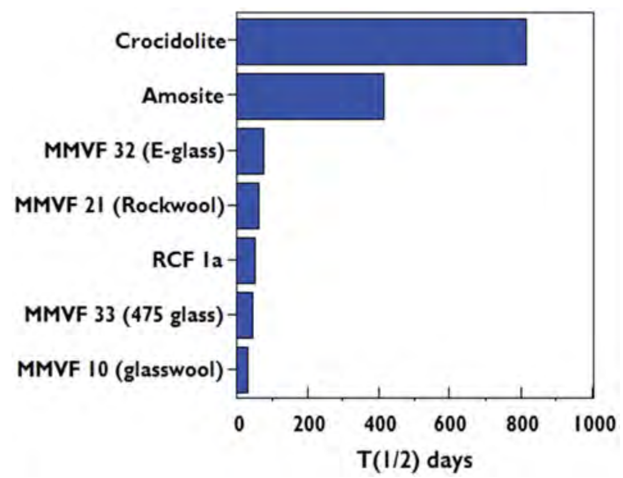


Figure 1. Weighted half-times (days) in the pulmonary region for amphibole asbestos and selected SVFs (Greim et al., 2014; Hesterberg et al., 1998; Maxim et al., 2006).

(Bellmann et al., 2001; Brown et al., 2000; Mast et al., 2000a,b]). As can be seen, RCF are more durable and biopersistent than several other SVFs, although very much less biopersistent than amphibole asbestos (see data from various sources summarized in Brown et al., 2005; Greim et al., 2014; Matsuzaki et al., 2015; Maxim et al., 2006). The averagely weighted half-time for RCF in rodents from several studies is approximately 50 days. There are no half-time data in humans, however, Lockey et al. (2012) noted that RCF can persist in human lung tissue for as much as 20 years.

### Animal tests and hazard classification

The earliest animal study, published in 1956 (Gross et al., 1956) on male rats exposed by intratracheal injection, concluded that RCF was no more hazardous than a "nuisance dust", but later studies conducted in the 1980s (Davis et al., 1984; Smith et al., 1987) and 1990s called this conclusion into question. Chronic nose-only studies on rats and hamsters conducted at the Research and Consulting Company (RCC) (then located in Geneva, Switzerland) indicated that nose-only inhalation exposure to high concentrations of RCF, resulted in fibrosis and tumors (for reviews and references see Greim et al., 2014; Mast et al., 1995a,b; McConnell et al., 1995; Mast et al., 2000a; NIOSH, 2006; Utell & Maxim, 2010). In 1988, an IARC Working Group reviewed the available evidence for RCF and placed RCF in Group 2B (possibly carcinogenic to humans). This classification was reaffirmed by a subsequent Working Group meeting in 2001 (IARC, 2002), which concluded that there was sufficient evidence in experimental animals but inadequate evidence in humans for the carcinogenicity of refractory ceramic fibers. Later analyzes, however, indicated that the RCC animal studies were compromised by overload, a factor that has made it difficult to derive accurate estimates of risk by extrapolation of animal study results (Brown et al., 2005; Drummond et al., 2016; Greim et al., 2014; Maxim et al., 2003; NIOSH, 2006; Utell & Maxim, 2010). Notwithstanding limitations of the animal studies, these results prompted concern that exposure to RCF might lead to similar health effects to those for various types of asbestos.

Harrison et al. (2015) provide a discussion of regulatory approaches in both the US and Europe. Useful discussions of RCF carcinogen classification and setting occupational exposure limits (OELs) in Europe can also be found in DECOS (2011), Greim et al. (2014) and SCOEL (2011). SCOEL recommended an OEL of 0.3 fibers/ml based on a calculated no-effect level for impact on lung function. OELs vary by country in Europe from 0.1 f/ml to 2.0 f/ml (Refer Table 3 of Harrison et al., 2015).

## Product stewardship program

Beginning in the late 1980s, producers of RCF developed a unified and comprehensive industry-wide product stewardship program (PSP) to assess and control possible risks associated with the production and use of RCF-containing products. The PSP was developed and administered through a series of organizations including (in chronological order) the Thermal Insulation Manufacturers Association (TIMA), the Refractory Ceramic Fibers Coalition (RCFC) and the HTIW Coalition in the US and through similar organizations, including ECFIA in Europe and the Refractory Ceramic Fiber Association (RCFA) in Japan. This comprehensive multi-faceted program includes health research (epidemiology studies and medical surveillance), workplace monitoring, exposure assessment, development of workplace controls to reduce exposure in both production plants and end-user facilities, product research (to develop less biopersistent fibers), special studies (emissions, energy savings, waste generation rates and possible substitutes) and a communications outreach component [see Maxim et al. (2008) for more detail]. The voluntary PSP in the US has been conducted under regulatory agency oversight (from 1993 to 1998 by USEPA and from 2002 onwards by OSHA). Annual reports are written to OSHA summarizing PSP progress, exposure measurements and recent developments in toxicology and epidemiology. The most recent annual report to OSHA (Everest Consulting Associates, 2017) provides additional detail on the product stewardship program.

## Epidemiology studies prior to 2010

The results of animal studies on the toxicity of RCF raised questions about possible adverse respiratory effects of exposure to these fibers in humans. These have been addressed in a series of epidemiology studies. Relevant summaries of epidemiology studies prior to 2010 are given in IARC (2002) and Utell & Maxim (2010). Additional comments are provided below.

One of the early epidemiology studies was reported by Chiazze et al. (1997). Costa & Orriols (2012) summarized the results of this study as follows:

> Chiazze et al. (1997) carried out a case–control study in men with LC [lung cancer] from a cohort of 2933 workers at a continuous fiberglass filament factory [in Anderson, South Carolina]. They assessed the exposure to fiberglass, asbestos and RCF, among others. The risk for LC was lower in those exposed to RCF compared with the controls. [Material in square brackets added for clarity.]

Carel et al. (2007) reported on a multicenter case–control study in six Central and East European countries and the United Kingdom. Occupational and demographic data were collected from 2205 newly diagnosed male lung cancer cases and 2305 controls. The study did not find a carcinogenic effect of exposure to MMVF or RCF; however, the power of this study was low. The study found a significant association between asbestos exposure and lung cancer in the United Kingdom but failed to observe a similar association with asbestos exposure among subjects in other European countries.

Marchand et al. (2000) reported results of a case–control study of the relationship between occupational exposure to asbestos and man-made vitreous fibers (including RCF) and laryngeal and hypopharyngeal cancer. This study involved 315 incident cases of laryngeal cancer, 206 cases of hypopharyngeal cancer and 305 hospital-based controls with other types of cancer, all recruited in 15 hospitals in six French cities. These investigators concluded that exposure to asbestos resulted in a significant increase in the risk of hypopharyngeal cancer (OR =1.80, 95% CI: 1.08–2.99) and a non-significant increase in the risk of laryngeal cancer (OR =1.24, 95% CI: 0.83–1.90). Exposure to mineral wools was of borderline significance for the risk of hypopharyngeal cancer (OR =1.55, 95% CI: 0.99–2.41), and not significantly associated with the risk of laryngeal cancer (OR =1.33, 95% CI: 0.91–1.95). No significant results were observed for the other MMVFs including RCF.

The most comprehensive series of epidemiology studies on occupational RCF exposure was sponsored by the industry as part of the PSP and initiated at the UC in the US and at the Institute of Occupational Medicine (IOM) in Europe. The earlier results of morbidity (US and Europe) and mortality (US) studies have been described/reviewed in several publications (Burge et al., 1995; Cowie et al., 2001; LeMasters et al., 1998, 2003; Lockey et al., 1996, 1998, 2002; McKay et al., 2011; Trethowan et al., 1995; Utell & Maxim, 2010). Elements of these studies were also included in a study of Australian ceramic fiber production workers (Rogers et al., 1997). As of 2010, these studies indicated that occupational exposure to RCF resulted in:

- Respiratory symptoms (e.g. dyspnea, wheezing, chronic cough, chronic phlegm) "similar to those reported in other dust-exposed populations" (LeMasters et al., 1998);
- A statistically, but not clinically, a significant decrease in certain measures of respiratory function in one cross-sectional study (LeMasters et al., 1998) for certain subgroups (e.g. male current or former smokers);
- However, further longitudinal study (Lockey et al., 1998) revealed no excess decline in lung function;
- A statistically significant increase in the prevalence of pleural plaques (Lockey et al., 1996, 2002), but no evidence of parenchymal disease; and
- No increased deaths from lung cancer or, at that time, any cases of mesothelioma (LeMasters et al., 2003). The mortality study also found an unexpected, but statistically

significant, association with cancers of the urinary organs (more below).

To summarize, the available epidemiological data from several studies as of 2010 indicated that symptoms were similar to other dust-exposed populations; there was evidence of minor decreases in certain measures of lung function and a dose-related increase in pleural plaques, but no interstitial fibrosis or elevated lung malignancy rates.

## More recent results

### *Exposures*

Exposure monitoring and using engineering controls and improved workplace practices for exposure reduction have been key elements of the PSP. Exposures are monitored (based on a stratified random sampling plan) at plants/facilities operated both by RCF producers and customers. Exposures to RCF at manufacturing locations can occur during fiber production, processing or converting (e.g. vacuum forming) or manufacture or assembly of other specific product forms (e.g. modules), packaging and warehousing. At customer facilities, exposures can result from many of the same activities (except fiber manufacture) and additionally when installing, repairing or removing after-service furnace linings.

Exposures vary by the type of work performed (the exposed population is divided into eight functional job categories [FJCs]) and other factors (e.g. the form of the product, type of engineering controls and industrial segment). Data on exposures by functional job category in the US and Europe for various time periods are provided in several publications (Burley et al., 1997; Everest Consulting Associates, 2017; Maxim et al., 1994, 1997, 1998, 2000, 2008; Rogers et al., 1997).

A useful summary statistic is the weighted average fiber concentration (fibers per milliliter, f/ml or fibers per cubic centimeter f/cc), calculated by taking the weighted average (weighted by the estimated number of workers in each FJC) of the measured 8-h time-weighted average (TWA) fiber concentrations.

Figure 2 shows the time series of a weighted average of measured fiber concentrations for RCF producers and customers in the US over the period from 1990 through 2016. (Similar data are collected for European producers and customers.) Respirators are worn for some jobs, but the data plotted in Figure 2 do not include any correction for the assigned protection factors of the respirators. There are some data to indicate that fiber concentrations were even higher in the years before 1990. Shown also in Figure 2 (dashed lines) are the recommended exposure guidelines (REGs) over this same time period. (The REGs were established on the basis of prudence and demonstrated feasibility rather than an explicit risk calculation.) The current REG, 0.5 f/ml, is numerically identical to the REL established by NIOSH. NIOSH (2006) wrote a criteria document containing a detailed discussion of the rationale for setting this REL. As can be seen:

- Exposures at both RCF manufacturing plants and customer facilities have decreased substantially over this

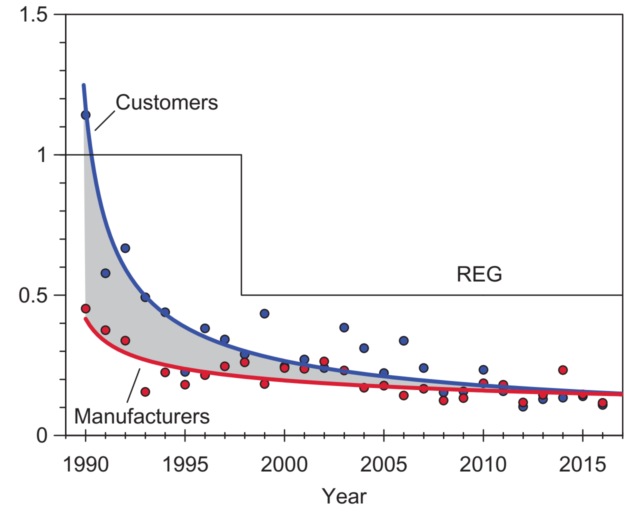


Figure 2. Time trends in weighted average TWA fiber concentrations at RCF manufacturers and customers (Everest Consulting Associates, 2017).

period. Weighted average exposures are now substantially lower than the US industry REG of 0.5 f/ml.
- The gap between exposures at customer and manufacturer facilities (shown by the shaded area in Figure 2) has decreased over time to the point that weighted average exposures are nearly the same for both groups.
- The rate of decrease in weighted average fiber concentrations has slowed in recent years, suggesting that the limits of present control technologies are being reached.

Notwithstanding the flattening of the exposure trends in more recent years, there has been significant progress in reducing exposures, which has materially reduced the cumulative exposure of workers (fiber-years/ml) employed in this industry compared to what would have occurred without the exposure reductions resulting from the PSP. Figure 3 shows for both manufacturer and customer measurements (see the shaded areas) that the cumulative exposure of either the manufacturer or customer cohorts beginning in 1990 when the first integrated industry-wide stewardship program was developed would have been substantially larger but for the exposure reductions brought about by the product stewardship program. The general shapes of these curves will remain the same even if there are no further exposure reductions.

### *Other exposure studies*

Zhu et al. (2015a) explored the relationship between mass dust and fiber concentrations in a plant producing RCF. The authors found that there was a broad correlation between these two measures, but the relationship was not sufficiently accurate to enable reliable predictions. This finding is consistent with earlier studies conducted by RCF producers in the US and Europe. Simply stated, dust concentrations are not an adequate surrogate for fiber concentrations.

Zhu et al. (2015d) presented data on fiber and total dust concentrations for various production jobs in a factory in

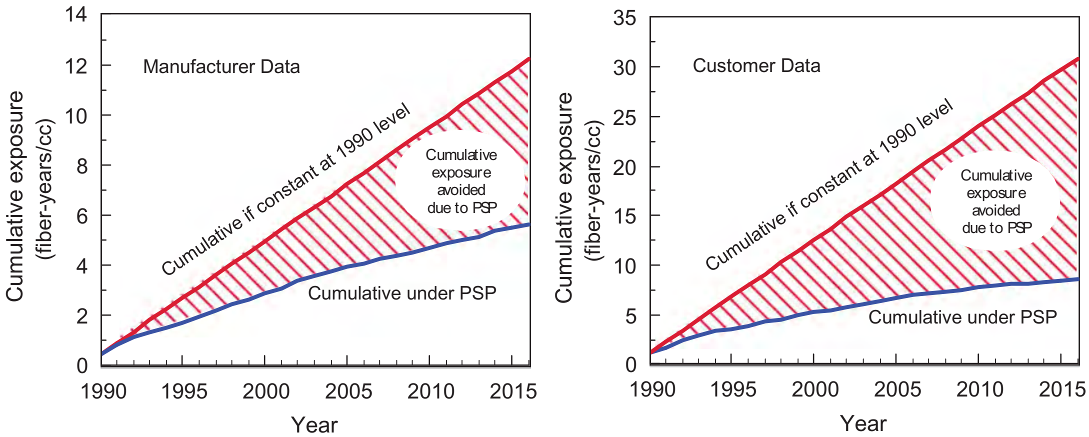


Figure 3. Graphs demonstrate cumulative exposure avoided by implementing the PSP program versus continued uncontrolled exposure at 1990 levels for manufacturer plants (left) and customers (right). Source: Everest Consulting Associates (2017).

China. Gravimetric dust concentrations ranged from 0.63 to 16 mg/m$^3$ and for fiber concentrations from 0.01 to 1.04 f/ml. Mean values for dust and fiber concentrations were 2.56 mg/m$^3$ and 0.19 f/ml, respectively. This study adopted "reference values" of 5 mg/m$^3$ and 0.5 f/ml for total dust and fiber concentrations, respectively. (The 0.5 f/ml reference value for fiber concentrations matches the industry REG and the NIOSH REL for RCF included in the HTIW Coalition PSP.) The authors also conclude that measurement of both total dust and fiber concentrations better reflects occupational exposures. The range and average fiber concentrations are broadly consistent with measurements made as part of the industry PSP, but differences in protocol preclude exact comparisons.

## Epidemiology studies since 2010

Several relevant papers describing the results of epidemiology studies have been published since 2010. These are summarized below.

Wild et al. (2012) published a case–control study among males aged 40–79, including confirmed primary lung cancer cases from all hospitals of a study region consisting of four administrative districts in the Northern part of the French Lorraine region near the German and Luxembourgian borders. Cumulative occupational exposure indices for various materials, including RCF and other MMMFs, were obtained from the questionnaires. Attributable fractions were computed from multiple unconditional logistic regression models. A total of 246 cases and 531 controls were included. The odds ratios (ORs) adjusted on cumulative smoking and family history of lung cancer increased significantly with the cumulative exposure indices to asbestos, polycyclic aromatic hydrocarbons and crystalline silica, and with exposure to diesel motor exhaust. The authors also noted:

> Neither RCF, MMMF, iron mining, stainless steel welding nor any other occupational exposure had any significant relation with lung cancer.

These results are consistent with the UC findings.

Lacourt et al. (2014) published a large case–control study aimed to test the hypothesis that there was an increased risk of pleural mesothelioma resulting from co-exposure to asbestos and RCF compared to asbestos exposure alone. Males were selected from a French case–control study conducted in 1987–1993 and from the French National Mesothelioma Surveillance Program in 1998–2006. Two population controls were frequency matched to each case by year of birth. Complete job histories were collected and occupational asbestos and RCF exposures were assessed using job exposure matrices. The dose–response relationships for asbestos exposure were estimated from an unconditional logistic regression model in subjects exposed to asbestos only and the second group of subjects exposed to both asbestos and RCF. The authors concluded that there is an increased risk of pleural mesothelioma resulting from co-exposure of asbestos and refractory ceramic fibers compared to asbestos exposure alone. The authors were somewhat guarded in noting:

> Further investigations are needed to confirm and understand the mechanisms of the effect [sic] modification of asbestos exposure in the presence of co-exposure to RCF.

This finding was surprising because other epidemiology studies have not disclosed any significant increase in the incidence of mesothelioma among cohorts exposed to RCF alone. In addition, the Carel et al. (2007) study (though limited in sample size) reported results that were inconsistent with the findings of Lacourt. Specifically, Carel et al. (2007) wrote:

> We did not find a carcinogenic effect of exposure to MMVF or for ceramic fibers. *Also, no synergistic effect—that is departure from a multiplicative joint effect—of simultaneous exposure to asbestos and MMVF could be shown.* [Emphasis added.]

The methodology of the Lacourt et al. (2014) analysis is similar to an earlier (Lacourt et al., 2013) study by many of the same authors that found a similar synergistic response between asbestos and mineral wool exposure. Carlsten & Georas (2014) reviewed the earlier Lacourt et al. (2013) paper and noted:

> Lacourt and colleagues reported a case–control study investigating associations between pleural mesothelioma and

occupational exposure to asbestos, mineral wool, and silica. A total of 1199 cases and 2379 control subjects were identified from different sources in France from 1987 to 1996 and 1998 to 2006. Although occupational exposure to asbestos is a well-known risk factor for pleural mesothelioma, the risks associated with mineral wool (which is used in insulation) and silica dust are less clear. The main finding was that occupational exposure to mineral wool was associated with a significantly increased OR for mesothelioma when adjusting for asbestos exposure (e.g. OR =2.5 for highest exposure group). No such associations were found for silica exposure in adjusted analyses, although a significantly higher OR was observed for silica exposure in the unadjusted subgroup analysis. These seemingly contradictory results could be the result of misclassification, the inability to independently separate exposures to the different compounds, or other factors, which were discussed in subsequent correspondence.

In the end, Carlsten and Georas concluded:

> Taken together, these data suggest that more research is needed to understand how mineral wool and other fibers interact to increase risk of mesothelioma over time.

Boffetta et al. (2014) reviewed the evidence on occupational exposure to SVFs (including RCF) and also analyzed an earlier (2013) Lacourt et al.'s study on co-exposure to asbestos and mineral wool. They showed that the conclusion reached by Lacourt and colleagues was sensitive to possible misclassification of asbestos exposure. They found that even a very small misclassification of asbestos exposure (95% sensitivity and specificity) offset the risk from SVF exposure and wrote:

> The fact that the elevated OR found in some of the case–control studies are reduced after adjusting for asbestos exposure and that they are not confirmed in cohort studies of production workers detracts from the credibility of a causal relationship between SVF exposure and mesothelioma risk. The combined evidence from epidemiologic studies leads to the conclusion that exposure to SVF is not likely to increase the risk of mesothelioma.

Boffetta et al. (2014) concluded:

> The epidemiological literature reviewed here provides support for the notion that SVF do not cause mesothelioma and is in line with these toxicological arguments that SVF are not biopersistent. The evidence from epidemiology and toxicology is therefore consistent with the hypothesis that non-biopersistent SVF pose no risk of mesothelioma to humans.

Thus, the Lacourt findings for both mineral wool and RCF must be viewed with some caution.

Gérazime et al. (2015) published another case–control (retrospective) study of male workers. The authors used data from ICARE, a population based case–control study conducted in France. Detailed lifetime tobacco and alcohol consumption, as well as complete occupational history, were collected. Analyses were restricted to men and included 1867 cases of head and neck squamous cell carcinomas, 2276 lung cancer cases and 2780 controls. Occupational exposure to RCF was assessed through a specific job-exposure matrix. The authors estimated odds ratios (ORs) and 95% confidence intervals (CIs), adjusted for age, residence area, tobacco smoking, alcohol consumption and cumulative exposure to asbestos with logistic models. The authors concluded that "although a moderate increase in risk cannot be excluded", occupational exposure to RCF was not significantly associated with risk of head and neck cancer (OR = 0.83; 95% CI = 0.64–1.10) or lung cancer (OR = 0.91; 95% CI = 0.72–1.16). Results of this study (no statistically significant excess in head and neck or lung cancer) are consistent with the UC results.

### UC mortality results since 2010

The UC mortality study is ongoing. The mortality study includes current and former male and female employees hired from 1952 through 1999 at two RCF manufacturing plants, one in New York and the other in Indiana who had at least 1-year RCF employment (see as LeMasters et al. [2003] for details). The latest published results of the prospective cohort study included all deaths as of 12/31/2015 (LeMasters et al. 2017). Participants ($N = 1119$) in the mortality study include current and former male and female workers at the New York ($N = 818$) and Indiana ($N = 301$) plants. The majority of workers are Caucasian (91%), male (84%) and current or former smokers (54%) and approximately half had self-reported prior asbestos exposure. The median age at death or time of follow up was 63.1 years, with a mean time since first exposure (latency) of 32.9 years and mean cumulative fiber exposure (CFE) of 46.1 fiber-months/cc At date of death or 12/31/2015, 87.3% had >20 years and 60.6% had >30 years time since first exposure. Exposure analyses enabled the identification of the most highly exposed subgroup in the cohort, workers ($N = 285$) with more than 45 fiber-months/cc RCF exposure.

Table 1 shows standardized mortality rates (SMRs) and two-sided 95% confidence intervals for deaths from malignant neoplasms (MNs) and selected other causes for both the entire cohort and most exposed group of RCF exposed workers in the latest update to the UC mortality study.

The pattern of SMRs is broadly similar to those reported earlier, but there are some differences related to kidney and bladder cancers and leukemia. Additionally, there was one reported, but unconfirmed mesothelioma in a worker with prior occupational exposure to asbestos – these points are discussed below.

LeMasters et al. (2017) also conducted a cancer incidence study. Since 2003 these investigators collected lung and urinary cancer incidence data using questionnaires for 1011 participants. There were four participants reporting respiratory cancers with 9.9 expected (Standardized Incidence Ratio (SIR) = 0.40) and two reporting urinary cancer with 6.4 expected (SIR = 0.31).

### Kidney and bladder cancers

New data on the prevalence of urinary cancers that indicate elevated SMRs for these diseases remain, but [according to LeMasters et al. (2017)] might have been caused by other factors rather than RCF exposure. Known risk factors for these cancers, including cigarette smoking, obesity, certain drugs, medical conditions and treatments and exposures to many other toxicants are summarized in Tables A1 (kidney

Table 1. SMRs and confidence intervals for full cohort ($N = 1119$) and most exposed group, abbreviated version, SMRs significantly elevated or reduced shown in boldface, excerpted from LeMasters et al. (2017).

| Group | Full cohort ($N = 1119$) | | | >45 fiber-months/cc ($N = 285$) | | |
|---|---|---|---|---|---|---|
| Cause | Observed deaths | SMR | 95% CI | Observed deaths | SMR | 95% CI |
| All causes | **234** | **0.73** | **0.64–0.83** | **93** | **0.79** | **0.64–0.97** |
| All cancers | 74 | 0.86 | 0.68–1.09 | 31 | 1.01 | 0.68–1.43 |
| MN respiratory | 24 | 0.83 | 0.53–1.24 | 8 | 0.75 | 0.32–1.48 |
| MN trachea, bronchus, lung | 23 | 0.83 | 0.53–1.25 | 8 | 0.78 | 0.34–1.55 |
| MN urinary organs | 8 | 1.80 | 0.78–3.55 | **6** | **3.62** | **1.33–7.88** |
| MN kidney | 4 | 1.72 | 0.47–4.39 | 3 | 3.60 | 0.74–10.52 |
| MN bladder and other urinary | 4 | 1.90 | 0.52–4.86 | 3 | 3.64 | 0.75–10.65 |
| MN other & unspecified site | 9 | 0.74 | 0.34–1.41 | 3 | 0.71 | 0.15–2.06 |
| MN mesothelioma | 1 | 2.86 | 0.07–15.93 | 1 | 7.85 | 0.20–43.76 |
| MN lymphatic and hematopoietic | 11 | 1.32 | 0.66–2.36 | 4 | 1.32 | 0.36–3.37 |
| Leukemia | **8** | **2.51** | **1.08–4.94** | 3 | 2.57 | 0.53–7.50 |
| Benign and unspecified MN | 1 | 0.94 | 0.02–5.26 | 0 | 0.00 | 0.00–9.67 |
| Heart diseases | **64** | **0.75** | **0.58–0.96** | 22 | 0.66 | 0.41–1.00 |
| Other dis. circulatory system | 15 | 0.68 | 0.38–1.13 | 5 | 0.59 | 0.19–1.39 |
| Diseases respiratory system | 25 | 1.01 | 0.65–1.49 | 12 | 1.26 | 0.65–2.20 |
| Dis. genito-urinary system | 2 | 0.35 | 0.04–1.26 | 1 | 0.47 | 0.01–2.60 |
| Other and unspecified causes | 8 | 0.76 | 0.33–1.50 | 2 | 0.57 | 0.07–2.06 |

NMN: malignant neoplasms; SMR: standardized mortality rates.

cancer) and A2 (bladder cancer) located in the Appendix. Most of these were not controlled for in the UC study. In reviewing the latest results, the UC investigators wrote:

> …the strongest risk factor for bladder and renal cancers is cigarette smoking (McLaughlin et al., 2006; Zeegers et al., 2000); half of the bladder and renal cancer deaths in the current study were known smokers. In addition, three of the four bladder cancer deaths were millwrights with potential occupational exposures associated with bladder cancer, including exposure to polycyclic aromatic hydrocarbons (PAH) (Behrman, 2003; Kogevinas et al., 2003; Reulen et al., 2008; Spinelli, 1989).

In assessing the plausibility of a possible relationship between RCF exposure and urinary cancers, it is reasonable to examine whether exposure to other fibers or to asbestos has been linked to urinary cancers. SVFs are the logical fibers for comparison (see below), but one article (Lauriola et al., 2012) concluded that asbestos exposure was associated with a statistically significant increase in SMR for renal neoplasia. However, two meta-analyses have failed to demonstrate a significant association between kidney cancer and asbestos exposure (Goodman et al., 1999; Sali & Boffetta, 2000). In fact, if the observed and expected renal cancers in the Lauriola et al., study are pooled with those from the Sali and Boffetta paper, then the resulting SMR is not statistically significant.

Additionally, Kannio et al. (1996) reported the following data regarding bladder cancer and asbestos exposure among patients with bladder cancer admitted for diagnostic or surveillance purposes to the Surgery Clinic, Turku University Central Hospital (Turko, Finland) between October and December 1988:

> Of the 28 primary bladder cancer cases in group 1, 17 (61%) had been exposed to asbestos at work. Of these, 16 (94%) were considered to have been definitely exposed. A crude OR of 2.8 (95% Cl = 0.9–8.4) was calculated for definite exposure to asbestos against no asbestos exposure and 2.4 (95% CI = 0.8–7.0) for the pooled category of definite to possible exposure against no asbestos exposure.

Although the odds ratios were elevated, the 95% CIs included 1.0 and, therefore, the elevations are not statistically significant.

Karami et al. (2011) investigated whether asbestos, as well as 20 other occupational dust exposures, were associated with renal cell carcinoma (RCC) risk in a large European, multi-center, hospital-based renal case–control study. The study included respondents from four Central and Eastern European countries (Moscow, Russia; Bucharest, Romania; Lodz, Poland; and Prague, Olomouc, Ceske-Budejovice and Brno, Czech Republic) between 1999 and 2003. In total, 1097 histologically confirmed RCC cases and 1476 controls were included in the study. These investigators found that among participants ever exposed to dust, significant associations were observed for glass fibers (OR: 2.1; 95% CI: 1.1–3.9), mineral wool fibers (OR: 2.5; 95% CI: 1.2–5.1) and brick dust (OR: 1.5; 95% CI: 1.0–2.4). Significant trends were also observed with exposure duration and cumulative exposure. No association between RCC risk and asbestos exposure was observed. (RCF was not included because of the small sample size.) The authors were careful to note the limitations of their study, but if the findings are correct, their results would provide a rationale for the contention that exposure to other SVFs, and potentially RCF, might be a risk factor for kidney or bladder cancer as reported in the UC studies. Among the reasons, why Karami et al. (2011) were cautious in claiming that exposure to SVFs might be a risk factor was the fact that their finding was not consistent with results from other epidemiology studies – a fact that prompted the authors to write (at various points in their article) the following cautionary remarks:

> The lack of supporting evidence from cohort studies, therefore, reduces the plausibility of an association between RCC risk and exposure to both glass and mineral wool fibers.

> Thus, it is unclear whether our findings of an association with glass and mineral wool fibers are real.

> Our observed associations also require replication before meaningful inferences can be concluded.

Table 2 summarizes the reported links between exposure to SVFs and renal or bladder disease from cohort or case–control studies [most of which were not discussed or cited

Table 2. Studies addressing links between exposure to man-made mineral fibers and either non-malignant or malignant kidney or bladder disease.

| Increase in kidney or bladder disease | Stud y type | Population and dust/fiber exposure | Results | References |
|---|---|---|---|---|
| Yes | Cohort | 2557 male workers in glass wool plant in Ontario, Canada. | The number of kidney cancers was nearly double that expected, both for plant-only and all workers. For the whole cohort, the 14 cases represented a significant excess (SIR =1.92; 95% CI [1.05, 3.21]). Study did not correct for smoking. Mortality from nephritis and nephrosis was significantly increased. Goldsmith & Goldsmith (1993) explored this issue by reviewing other literature and concluded that silica was likely to be the cause of the excess renal disease.<br>Earlier study published 1984 showed cancer of genitourinary organs for plant only and total cohort of:<br>Plant only: SMR =1.61; 95% CI [0.41, 4.39] and total: SMR =1.84; 95% CI [0.58, 4.43]. | Shannon et al. (1984, 2005) |
| Yes | Case–control | Large hospital-based (CEERCC) study of renal cancer conducted across four Central and Eastern European countries. | Among participants ever exposed to dusts, significant associations with renal cell carcinoma (RCC) were observed for glass fibers (OR =2.1; 95% CI [1.1, 3.9]) mineral wool fibers (OR =2.5; 95% CI [1.2, 5.1]) and brick dust. Significant trends were observed with exposure duration and cumulative exposure. | Karami et al. (2011) |
| No | Cohort | 5369 workers in mineral wool plant in Denmark. | Authors reported increase in cases of bladder cancer only among workers with $\geq$20 years since first employment. (4 bladder cancer cases compared to 1.6 expected O/E = 2.5; exact 95% CI [0.79, 6.03].) (*p* value reported in article 0.06 based on Chi-square test, improved *p* values are 0.1025 Mid-*p* exact tests or 0.1576 Fisher exact test.) No excess in kidney cancer found. | Olsen & Jensen (1987) |
| No | Case–control | Montreal multi-center of (inter alia) 100 kidney and 300 bladder cancer cases (1979–1983). | Study reported ORs for "synthetic fibers" [interpreted by Karami et al. (2011) to include glass and mineral wool] and kidney cancer OR =0.8; 95% CI [0.2, 2.8] and bladder cancer OR 1.6; 95% CI [0.9, 3.0]. Additional result for cases with substantial exposure (>15 years) for bladder cancer with borderline significance OR =2.1; 95% CI [1.0, 4.4]. | Siemiatycki et al. (1986) |
| No | Cohort | Cohort of 941 workers in the glass wool producing industry in Finland was followed for deaths in 1953–1981. | SIR for bladder cancer =1.09; 95% CI [0.03, 6.06]. Kidney cancer included in "other" category with non-significant SIR. | Teppo & Kojonen (1986) |
| No | Cohort | 3749 workers employed for at least 3 months in two Finnish glass factories (cohorts A and B) were followed up for cancer in 1953–1986 through the Finnish Cancer Registry. | SIR for kidney cancer (both sexes) = 0.35, based on 3 observed and 8.6 expected; 95% CI [0.07, 1.02].<br>SIR for bladder cancer (both sexes) = 0.97. Based on 9 observed and 9.3 expected; 95% CI [0.44, 1.84]. | Sankila et al. (1990) |
| No | Cohort | Mortality and cancer incidence was investigated among 2807 workers employed for least 1 year before 1972 at 11 Swedish companies manufacturing prefabricated wooden houses. A total of 1068 workers were exposed to MMVF used for insulation. | Mortality:<br>Bladder cancer SMR =0.98; 95% CI [0.26, 2.50]<br>Kidney cancer SMR =0.47; 95% CI [0.099, 1.38] | Gustavsson et al. (1992) |
| No | Cohort | 3539 male and female workers in three Swedish plants producing SVFs followed from 1952 to 1990. | SMR for bladder cancer =1.27; 95% CI [0.48, 2.77]. SMR for kidney cancer =1.4; 95% CI [1, 7.9]. | Plato et al. (1995) |
| No | Cohort | 22,002 production workers in man-made vitreous fiber production plants in Denmark, Finland, Norway, Sweden, United Kingdom, Germany and Italy, from 1982 to 1990. | There was no significant SMR for bladder cancer in the total cohort, those with $\geq$1 year employment or when partitioned among rock/slag wool, glass wool or continuous filament. (Total deaths from bladder cancer in entire cohort 35, SMR =1.07; 95% CI [0.74, 1.48].) | Boffetta et al. (1997) |

(*continued*)

**Table 2.** Continued

| Increase in kidney or bladder disease | Stud y type | Population and dust/fiber exposure | Results | References |
|---|---|---|---|---|
| No | Cohort follow up | A cancer incidence follow-up was conducted among 3685 rock-slag wool (RSW) and 2611 glass wool (GW) production workers employed for 21 year in Denmark, Finland, Norway, or Sweden and the standardized incidence ratios (SIR) were calculated on the basis of national incidence rates. | SIRs and 95% CIs for kidney cancer:<br>Total SIR =0.50; 95% CI [0.28, 0.83]<br>Rock/slag SIR =0.50; 95% CI [0.23, 0.95]<br>Glass wool SIR =0.50; 95% CI [0.18, 1.09]<br>SIRs and 95% CIs for bladder cancer:<br>Total SIR =1.06; 95% CI [0.80, 1.38]<br>Rock/slag SIR =0.91; 95% CI [0.62, 1.29]<br>Glass wool SIR =1.39; 95% CI [0.88, 2.08] | Boffetta et al. (1999) |
| No | Cohort | 11,373 male workers were who were employed for at least 1 year in the production of rock or slag wool (RSW), glass wool (GW) and continuous filament (CF) in 13 factories from seven European countries. | Increasing trend in mortality from non-malignant renal diseases. However, SMRs were not significantly elevated. | Sali et al. (1999) |
| No | Case–control | 47 cases of nephritis or nephrosis from Owens Corning mortality surveillance system. | In this analysis, there was no consistent relation between respirable fiber exposure and either nephritis or nephrosis. | Chiazze et al. (1999) |

Pooling the SMRs (Fixed effects model, see Morfeld et al., 2016) based on only the cohort studies listed in this table leads to the following pooled SMRs and corresponding 95% exact confidence intervals (http://www.openepi.com/SMR/SMR.htm) for bladder cancer – SMR =1.18.0, 95% CI [0.98, 1.41] and kidney cancer SMR =0.894, 95% CI [0.701, 1.124]. Neither result provides statistical evidence of elevated SMRs.

in the Karami et al. (2011) article] that underscore some of the limitations of this study. With very few exceptions, these study results do not support the contention that SVF exposure (at least glass wool or mineral wool exposure) is a risk factor in the malignant or non-malignant bladder or kidney disease. Although some of the studies summarized in Table 1 involved small sample sizes, there is more compelling evidence against this relationship in the various large well designed and executed cohort studies of Marsh and colleagues (Marsh et al., 1990, 2001a,b; Stone et al., 2004).

### *Leukemia*

The latest UC mortality study results (Table 1) indicated an excess of leukemia deaths in the full cohort (four acute myeloid, two acute unspecified and two chronic lymphocytic). However, there was no significant excess of leukemia (all types) in the group with the highest exposures. The fact that there is no apparent exposure–response suggests that the observed increase in leukemia deaths in the cohort is related to other risk factors, rather than RCF exposure. Table A4 (Appendix) summarizes the literature on causes, contributing factors or risk factors for various types of leukemia. (As these cases were all in adults, this table does not address factors for childhood leukemia.) Included in this table are occupational, lifestyle-related, environmental, medical procedures, genetic disorders and family history risk factors for various subtypes of leukemia (most of which were not measured or controlled for in the UC study). Among the more likely explanations for this finding are occupational exposures to certain chemicals and lifestyle-related risk factors, such as smoking and obesity.

Although occupational exposures to certain chemicals have been attributed to leukemia, exposure to fibers has not been shown to be a risk factor for leukemia (see below) and such an effect is arguably implausible, given what is known about fiber toxicology and epidemiology. Occupational exposure to various fibers has been included in several studies of adverse health effects, but leukemia has not been the endpoint of concern because of the assumption that fiber exposures are more likely to be associated with malignant or non-malignant lung-related diseases. Nonetheless, several studies on health effects of exposure to other fibers (PVA, rock/slag wool, glass fibers and asbestos) present data relevant to other malignant diseases, including leukemia. Shown below is a short summary of these data by type of fiber.

- *Polyvinyl alcohol (PVA)*: Morinaga et al. (1999) studied a cohort of male workers in a Japanese factory producing PVA. This small study (38 deaths among 454 PVA fiber exposed workers and 210 deaths among 2441 non-exposed workers) calculated SMRs and confidence intervals for several malignant diseases, including leukemia (ICD8 204–209). The calculated SMR and 95% confidence interval for leukemia among exposed workers were SMR = 0 and (95% CI; 0–5.52), respectively, whereas the non-exposed group actually had a higher SMR; SMR = 1.53 (95% CI; 0.49–3.57).

- *Fiberglass (FG)*: Marsh et al. (2001a) performed the most comprehensive study on FG workers in the US, including 32,110 persons at risk and 935,581 person-years at risk. As with other fiber studies, the focus of this study was on malignant and non-malignant lung diseases. Nonetheless, the study reported observed fatalities (199) for "all lymphatic and hematopoietic tissue diseases (ICD 200–209)", including leukemia. The SMRs were not elevated when compared to either US or corresponding local county rates. For example, the SMR and corresponding confidence interval compared to US national rates were SMR = 0.92 and (95% CI; 0.8–1.06), respectively.
- *Rock-slag wool (RSW)*: Marsh et al. (1996) published results of a large epidemiological study of workers exposed to rock-slag wool (RSW) in the US. Although the focus of this study was on respiratory cancers, data were available on lymphopoietic cancers (ICD8 200–209), including leukemia. Two cohorts were included and SMRs were not significantly elevated for either cohort.
- *Man-made mineral fibers (MMMFs) (Countries other than the US)*: Several authors have reported results for various MMMFs, including fiberglass, rock and slag wool in countries other than the US.
  - Claude & Frentzel-Beyme (1984) studied a cohort of workers in a German rock-wool factory; the exposed and reference cohorts included male employees, consisting of 2096 males in the former and 1778 males in the latter group. The calculated risk ratio for "leukemia and lymphatic system (200–207)" was 0.57 (95% CI; 0.1 – 3.37).
  - Simonato et al. (1986) reported results of a study of 24,609 workers in 13 European factories (Denmark, Finland, Germany, Italy, Norway, Sweden and the UK) that produced continuous filament, glass wool, rock wool and slag wool. Based on 17 leukemia deaths (both sexes) the calculated SMR and confidence interval were 0.80 and (95% CI; 0.47–1.28), respectively.
  - Plato et al. (1995) reported a follow-up study of 3539 workers (74, 043 person-years) in three Swedish plants producing fiberglass or rock wool. The calculated SMR and 95% confidence interval for deaths from leukemia were 0.89 and (95% CI; 0.33 – 1.93), respectively.
  - Boffetta et al. (1999) published the latest update to the European studies of MMMFs among 3,685 rock-slag wool (RSW) and 2,611 glass wool (GW) production workers employed for 21 years in factories in Denmark, Finland, Norway or Sweden, and the standardized incidence ratios (SIRs) were calculated on the basis of national incidence rates. For the entire cohort (male and female, RSW and GW), the calculated SIR and 95% CI for leukemia were 0.92 and (95% CI: 0.53–1.50), respectively.
  - Adegoke et al. (2003) reported a population-based case–control study of 486 leukemia subjects and 502 healthy controls residing in Shanghai from 1987 to 1989. Adjusted odds ratios (OR) were calculated for the self-reported association between occupational factors and leukemia risk. Among the various chemicals included in the study was a substance described as "synthetic fiber dust" (otherwise undefined). The calculated odds ratio (OR) and 95% confidence interval for leukemia (all forms) among those exposed to "synthetic fiber dust" were 2.0 and ((95% CI: 1.2–3.5), respectively. The relevance of this study is unclear because no definition or characterization of "synthetic fiber dust" is given.
- *Asbestos*: Asbestos (at least certain forms) has been proven to cause (among others) various malignant and non-malignant lung diseases. A few studies have been published that provide evidence regarding leukemia.
  - Selikoff (1990) provided data on causes of death among 17,800 asbestos insulation workers in the US and Canada, from 1 January 1967 to 31 December 1986 – observed deaths from all causes totaled 4951 based on best evidence. The SMR and 95% confidence interval based on 33 observed deaths (best evidence) for leukemia were 1.148 and (Fisher exact test 95% CI; 0.79–1.61), respectively, which Selikoff included in a table labeled "cancers not found with increased incidence".
  - Kishimoto et al. (1988) & Chinushi et al. (1990) published case reports on a total of three persons admitted to Kure Kyosai Hospital, Kure, Japan with leukemia had evidence of asbestos exposure. In a later publication, Kishimoto (1992) noted that of 10 cases of leukemia, five showed evidence of asbestos exposure.
  - Goodman et al. (1999) performed a meta-analysis of eight studies covering asbestos exposure and leukemia. The calculated meta-SMR and 95% confidence interval were 0.95 and (0.80, 1.13), respectively.
  - Seidler et al. (2010) reported results of a large multicenter case–control study in Germany and Italy that examined the relationship between asbestos exposure and various diseases. Among various diseases, there were a total of 149 cases of chronic lymphocytic leukemia (CLL). Adjusted odds ratios (ORs) and confidence intervals were calculated as a function of fiber-years of asbestos exposure. All ORs (in each cumulative exposure category) were close to 1, there was no dose–response, and all confidence intervals included 1.0. The authors concluded: "We observed no statistically significant association between cumulative asbestos exposure and the risk of any lymphoma subtype".

LeMasters et al. (2017) commented on the leukemia results in the UC study as follows:

> The elevated leukemia SMR in the total cohort, but not in the high exposed group, was a new and unexpected finding. These eight cases had job tasks that included machine operator (4), millwright (2), welder (1) and maintenance (1). Exposures associated with leukemia and, in particular, acute myeloid leukemia (50% of cases in the current study) include ionizing

radiation and benzene (Polychronakis et al., 2013; Tsai et al., 2014).

On a weight of evidence basis, we conclude that these studies fail to implicate exposure to any of several types of fibers as a cause or contributing factor for leukemia. Because of this and the absence of a dose–response [one of the Hill (1965) criteria], it is likely that the observed leukemia deaths are caused by some factor other than exposure to RCF or any of these other fibers, leaving occupational exposure to other materials or lifestyle factors as the likely explanation for the findings. Nonetheless, leukemia will continue to be included in the ongoing mortality study.

## Mesothelioma

As noted above there was one reported, but unconfirmed, death from mesothelioma in the RCF-exposed cohort.

Although the calculated SMR was not significant, it is appropriate to examine this case further. The worker in question had self-reported occupational asbestos exposure working as a vehicle mechanic for 6.5 years. Numerous studies have shown that vehicle mechanics are exposed to asbestos-containing materials, which can result in adverse health effects, including lung cancer and mesothelioma (Castleman et al., 1975; Egilman & Billings, 2005; Egilman & Longo, 2012; Finkelstein, 2008; Freeman & Kohles, 2012; Hansen, 1989; Huncharek, 1990, 1992; Imbernon et al., 2005; Kakooei et al., 2011; Lemen, 2004; Michaels & Monforton, 2007; Roggli et al., 2002; Welch, 2007). For example, in the analysis of 1445 cases of mesothelioma studied by Roggli et al. (2002), the automotive sector ranked eighth in terms of the number of mesothelioma cases among 12 industrial sectors evaluated. Epidemiology studies of occupationally exposed cohorts are less easy to interpret, with some studies or analyzes concluding that automobile mechanics have an elevated risk. Nonetheless, other studies and meta-analyzes indicate that mesothelioma risks are not significantly elevated (Aguilar-Madrid et al., 2010; Butnor et al., 2003; Dotson, 2006; Finley et al., 2012; Garabrant et al., 2016; Goodman et al., 2004; Hessel et al., 2004; Laden et al., 2004; Paustenbach & White, 2012; Peto et al., 2009; Rake et al., 2009; Richter et al., 2009; Teschke et al., 1997; Wong 2001, 2006). This certainly does not mean that the incremental risks are zero. As noted by Lemen (2004):

> The results of the exposure studies, experimental studies, case reports, and findings from the equivocal epidemiological studies by no means exonerate the brake mechanic from being susceptible to a causal relationship between asbestos exposure and mesothelioma.

Several articles have been published that address the relationship between mesothelioma and low levels of asbestos exposure (Iwatsubo et al., 1998; Rödelsperger et al., 2001). Moreover, the results of Roggli et al. (2002) clearly show that vehicle mechanics have developed mesothelioma.

Of greater probable relevance, in our judgment, is the history of other jobs held by this worker. LeMasters et al. (2017) report:

> Other prior jobs this individual reported that have historically been associated with potential asbestos exposure included machinist apprentice overhauling railroad steam engines (Schenker et al., 1986; Roggli et al., 2002) in the early 1950s (only exposure he reported was cutting oil), aviation electrician from 1952 to 1956 in the US Navy (reported exposure was to aviation fuel) and working as a technician in fuel systems (reported exposures were fuel and cleaning solvents) for South Bend Bendix Aviation from the mid-1950s to early 1970s. Bendix Corporation manufactured asbestos containing friction brake products.

Shown below are additional materials that address possible asbestos exposure in these jobs.

- *Asbestos exposure and railroads*: Numerous epidemiological studies have been published of workers in the US and various countries in Europe and Asia showing that those workers employed performing various jobs in the railroad industry were exposed to asbestos and experienced a statistically significant excess of various asbestos-related diseases, including mesothelioma (Battista et al., 1999; Garshick et al., 1987; Gasparrini et al., 2008; Gerosa et al., 2000; Hosoda et al., 2008; Hjortsberg et al., 1988; Huncharek, 1987; Malker et al., 1985; Maltoni et al., 1995; Mancuso, 1983, 1988, 1991; McDonald & McDonald, 1989; Ohlson et al., 1984; Oliver et al., 1985; Plato et al., 2016; Roelofs et al., 2013; Roggli et al., 2002; Rolland et al., 2010; Schenker et al., 1986; Tessari et al., 2004). According to Roggli et al. (2002) Table 1 of this paper, railroad workers ranked seventh in the top 12 industry types based on their large (1445 cases) sample of mesothelioma deaths.
- *Asbestos exposure and US Navy*: Until efforts to use substitute materials for asbestos on US Navy ships (and ships from other nations) and enhanced asbestos control measures accelerated in the 1970s (Anonymous, 1979; Franke & Paustenbach, 2011; Harries, 1968; Mangold et al., 1970; Rushworth, 2005; Strand et al., 2010; Twight 1991; Winer & Holtgren, 1976), both amosite and chrysotile asbestos was used extensively on US Navy ships. Nearly all Navy personnel aboard ships had some asbestos exposure, even in berthing quarters and mess halls, particularly prior to 1980. Numerous studies have evaluated the health risks to seamen and those employed in shipyards (Bianchi et al., 2001; Greenberg, 1991; Kurumatani et al., 1999; Roggli et al., 2002; Selikoff & Hammond, 1978; Selikoff et al., 1990). With respect to mesothelioma specifically Roggli et al. (2002) noted that the numbers of mesothelioma cases were greatest in the shipbuilding and US. Navy sectors among his sample of 1445 mesothelioma cases [see illustration from Table 1 of Roggli et al. (2002)]. Similar results were reported in the Trieste-Monfalcone area, Italy (Bianchi & Bianchi, 2009; Bianchi et al., 2001) and the United Kingdom (Peto et al., 2009).
- *Bendix Aviation*: This plant made both automobile and aircraft brake shoes and is listed on several websites as a location where asbestos exposure occurred.

One of the difficulties of epidemiological studies of fibers is that some members of the cohort may have also had prior asbestos exposure, as was the case with studies of other SVFs including RSW (Marsh et al., 2001b; Boffetta et al., 1997, 2014) and glass wool.

### Pulmonary function studies

LeMasters et al. (2017) also conducted pulmonary function studies on RCF-exposed workers. Among those with localized pleural thickening (LPT), percent predicted FVC and $FEV_1$ differed from those without LPT by <3%, a value judged clinically insignificant.

Zhu et al. (2015b) compared various measures of pulmonary function (FVC, $FEV_1$ and $FEV_1$/FVC) for 265 manufacturing and processing workers exposed to RCF with a group of 273 workers in a Chinese facility exposed to noise only. The exposed group was subdivided into subgroups based on gravimetric measurements of total dust and fibers. This study reported, *inter alia*, that the exposed group had statistically significantly lower mean values of FVC, $FEV_1$ and $FEV_1$/FVC (clinical significance unstated). The study reported that pulmonary effects were positively correlated with the fiber concentration (to a degree greater than total dust). This study did not consider the effects of initial weight or weight gain among the subjects. Unlike McKay et al. (2011), these investigators did not report any longitudinal analysis. McKay et al. (2011) offered the following comments on their longitudinal analysis of the US cohort:

> In conclusion, no consistent longitudinal decline in FVC or $FEV_1$ with increasing RCF exposure category was observed, although cross-sectional changes were observed for subjects in the highest exposure category. Critical to this analysis was the recognition that lung function declines with age are non-linear and accelerate in older age groups who also have the longest duration of exposure. To our knowledge, this specific analysis strategy has not been published for evaluating longitudinal change in lung function among adults, although a similar methodology has been used in children.

It is possible that Zhu and colleagues would have reached similar conclusions had they conducted a longitudinal analysis.

### Pleural plaques

As noted above, the X-ray studies conducted by the UC researchers have shown a significant relationship between RCF exposure and the development of pleural plaques. The overall rate of pleural changes reported by LeMasters et al. (2017) in their most recent publication was 6.1%, which increased across exposure categories reaching, in the highest CFE category, 21.4% (adjusted odds ratio (aOR) = 6.9, 95% CI 3.6–13.4) and 13.0% (OR = 9.1, 95% CI 2.5–33.6) for all subjects and for those with no potential asbestos exposure, respectively. The small increase in pleural plaques is not surprising as the presence of plaques is likely to be related to increasing latency. Prevalence among recent hires (>1985) was similar to the background. Interstitial changes were not elevated. And, as noted above, localized pleural thickening was found to be associated with small decreases in spirometry.

The finding that pleural plaques are related to RCF exposure is of potential concern because pleural plaques are widely considered to be a marker of exposure to fibers – particularly, but not exclusively, asbestos [see Clarke et al. [2006] for a list of other reported cases of pleural plaques]. Because occupational asbestos exposure has been shown to lead to a variety of adverse health outcomes, including asbestosis, lung cancer and mesothelioma in exposed cohorts, it is plausible to believe that there would be a correlation between the prevalence of pleural plaques and these asbestos-related diseases. Useful perspectives on this possibility are provided by Utell & Maxim (2010).

Three more recent papers have been published on the relevance of pleural plaques:

- Moolgavkar et al. (2014) published a detailed review and critique of U.S. EPA's risk assessments for asbestos. EPA regarded pleural plaques an "adverse condition" and developed a reference concentration (RfC) based on this endpoint. They concluded:

  > Taken together, the totality of evidence suggests strongly that pleural plaques are markers of asbestos exposure with little or no clinical significance. Thus, pleural plaques do not appear to satisfy EPA's own definition of an adverse condition.

- Kerper et al. (2015) published a systematic review of the relation between pleural plaques and lung function and concluded that the weight of evidence indicates that pleural plaques do not impact lung function and that the observed associations are most likely due to unidentified abnormalities or other factors. This result is also consistent with UC findings on the RCF-exposed cohort.
- Maxim et al. (2015) reviewed the extensive literature relating the linkage between pleural plaques and lung impairments/diseases and concluded that the available evidence supports the contention that, absent any other pleural disease, the presence of pleural plaques does not result in respiratory symptoms or clinically significant impacts on lung function. Pleural plaques are not premalignant, that is, they do not progress to malignant tumors (lung cancer or mesothelioma). For certain types of asbestos, the development of pleural plaques is statistically correlated with malignant disease, but the evidence is consistent with the hypothesis that pleural plaques (without other pleural diseases) are a marker of exposure, rather than an independent risk factor (see also IIAC, 2008).

### Dermal studies

Zhu et al. (2015c) also examined the effects of exposure to RCF (fibers) and dust on workers' skin by comparing effects on 281 RCF-exposed manufacturing and processing workers with a control group of 274 workers in a Chinese facility. The study found that skin itching symptoms and contact dermatitis were significantly correlated with total gravimetric dust measurements, but not with fiber concentrations. This finding is consistent with other studies of skin irritation related to exposure to SVFs. Some (but not all) persons exposed to various SVFs, including glass fibers (ATSDR, 2004; Jolanki et al., 2002; Possick et al., 1970; Sertoli et al., 1992; Tarvainen et al., 1994), mineral wool (Petersen & Sabroe, 1991), rockwool (Kieć-Świerczyńska & Szymczk, 1995) and RCF (Kieć-Świerczyńska & Wojtczak, 2000) as well as PCWs develop adverse skin reactions (sometimes termed "fiberglass itch" or more properly irritant contact dermatitis [ICD]) including folliculitis (a common skin condition in which hair follicles become inflamed), irritant symptoms including itching without rash on arms, face or neck, and burning of eyes. With most SVFs and PCWs, this is believed to be a physical (mechanical rather than chemical) phenomenon, although some binders or coatings are believed to be sensitizing agents that also cause dermatitis. Though perhaps uncomfortable, this disease is not life-threatening and most irritation is described as "mild". Unlike most respiratory illnesses resulting from exposure to respirable fibers (which may have a latency – the time from first exposure until the disease manifests itself – which can be 15–50 years), dermatitis arises in some subjects exposed for a short time (Sertoli et al., 1992). Thus, although dermatitis is typically a less severe illness than many respiratory illnesses, it is "obvious" and appears promptly, so it is likely to be recognized.

Numerous authors have studied the effects of dermal exposure to various SVFs and dermatitis. Table A3 provides a summary of some of the relevant literature including review articles, focus groups, patch or rubbing tests, case reports and epidemiological studies.

Overall, these and other studies conclude that irritant contact dermatitis is associated with exposure to various SVFs/PCWs with diameters that are larger (~5 µm or larger) than those of respirable fibers and typically becomes less pronounced with continued exposure (ATSDR, 2004; Possick et al., 1970; Sertoli et al., 1992). As noted by Sertoli et al. (1992):

> The pathogenic effect of fiberglass on the skin is directly proportional to the diameter and inversely proportional to the length. Fiberglass is harmful only if its diameter is greater than 4.5 µm or, according to other authors, 5 µm.

There is very little evidence of irritant contact dermatitis being caused by or associated with exposure to SVFs with diameters in the respirable range. But, because fibers with larger diameters weigh proportionally more than thinner fibers, it is reasonable that a gravimetric measure would be superior to fiber number concentrations as an indicator of the potential for ICD as reported by Zhu et al. (2015c).

### Other analyses

Several other potentially relevant works (shown below in chronological order) have been published since 2010.

The Scientific Committee on Occupational Exposure Limits (SCOEL, 2011) published a review of RCF toxicology and epidemiology and developed a no observed adverse effect level (for possible impacts on pulmonary function) of 0.3 f/ml. The SCOEL report acknowledged the lack of evidence of carcinogenicity from epidemiology studies, but based on the results of the animal studies concluded:

> From the available information it is concluded that the genotoxic effects observed in the different studies are secondary so that RCF are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported

Some German scientists concluded based on IP injection study results that RCF was as potent as amphibole asbestos in causing lung diseases. Walker et al. (2012a,b) tested the hypothesis that RCF was as potent as amphibole asbestos in causing lung cancer or mesothelioma. These investigators found that a cohort occupationally exposed to asbestos at identical levels to the RCF exposed cohort would have experienced significantly greater mortality than actually observed. Otherwise, there is no new risk analyses published since the Utell & Maxim (2010) review article. Earlier risk estimates based on extrapolation from animal studies span a very wide range (NIOSH, 2006; Maxim et al., 2003).

Costa & Orriols (2012) published a review article dealing with MMVF (including RCF) and the respiratory tract. Among other topics, this review commented on the finding that there was no parenchymal lung disease reported in the UC and Cowie et al., (2001) RCF studies as follows:

> In spite of this, in most of the cohort studies in MMMF factory workers, exposure levels were estimated to be low; therefore, it is considered that the epidemiological studies may not have detected cases of pulmonary fibrosis for this reason.

Whether or not this conjecture is correct, it underscores the prudence of continuing efforts to maintain or reduce occupational exposures, a major objective of the industry PSP.

As noted above, the industry PSP also includes a product research component, focused on the development of possible substitutes for present high-temperature insulation materials with less potential for toxic effects. This effort led to the development of a new class of materials, termed alkaline earth silicate (AES) wools. AES wools are less biopersistent fibers capable of substituting for RCF in some (but not all) applications. Brown & Harrison (2012) published an article describing these materials and the history of their development.

Greim et al. (2014) explored analogies (e.g. fiber dimensions, breakage mechanism and measured biopersistence in animal inhalation studies) between RCF and conventional mineral wool and concluded that the risks associated with occupational exposure are likely to be comparable for these two fibers. This is of interest because large and robust epidemiological studies of occupational exposure to mineral wool found that risks of lung cancer and mesothelioma are not elevated. The evidence was sufficiently compelling that IARC downgraded the carcinogen classification for glass and mineral wool from 2B to 3.

Boffetta et al. (2014) (see above) completed a systematic review of occupational exposure to SVFs and mesothelioma. This comprehensive review paper examined the epidemiological (case–control and cohort) and toxicological evidence for a linkage between occupational exposure to SVFs (including RCF) and mesothelioma. These investigators concluded that the combined evidence from epidemiology and toxicology "provide little evidence that exposure to SVF increases the risk of mesothelioma".

The HTIW Coalition and ECFIA continue to publish outreach materials in English and several other languages (as part of the product stewardship program) designed to inform workers about good working practices for handling RCF and other high temperature insulation wools (see e.g. http://www.ecfia.eu/files/ecfia-cartoon-redesign-english-v1_0-2014-04.pdf and http://guidance.ecfia.eu/index.htm) as do other agencies (HSE, 2008; NIOSH, 2006).

Matsuzaki et al. (2015) published a review article on biological effects of RCF exposure. Among their concluding remarks they wrote:

> Thus, given the biological effects of RCF previously reported in the literature, it is necessary to consider further monitoring in addition to the development of measures to prevent adverse health effects caused by exposure to RFCs.

Harrison et al. (2015) wrote a recent review of regulatory risk assessment approaches for synthetic mineral fibers (including RCF). They pointed out that occupational exposure limits (OELs) for RCF developed by regulatory and advisory bodies in various countries varied by more than an order of magnitude and argued that:

> The resulting differences in established OELs prevent consistent and appropriate risk management of SMF worldwide, and that development of a transparent and harmonised approach to fibre risk assessment and limit-setting is required.

Andujar et al. (2016) published a 5-year update on the relationships between malignant pleural mesotheliomas and exposure to asbestos and other elongated mineral particles. The article reviewed earlier studies published by some of the same authors, which (as noted above) reported an apparently synergistic relation between exposure to asbestos and certain mineral fibers, including mineral wool and RCF. This article recapitulated the findings and some of the limitations of these earlier studies and (in a more cautious vein) noted:

> While the issue of the simultaneous effect of asbestos and other mineral particles needs to be further explored in reality, the hypothesis of a synergistic joint effect needs to be considered.

Drummond et al. (2016) published a review article that examined the relationship between the results of intra-pleural and intraperitoneal studies with those from inhalation and intratracheal tests for the assessment of pulmonary responses to inhalable dust and fibers. They concluded:

> For some of the fibrous material reviewed, there is conformity between the results of intraperitoneal and inhalation tests such that they are either consistently positive or consistently negative. For the remaining fibrous materials reviewed, intraperitoneal and inhalation tests give different results, with positive results in the intraperitoneal test not being reflected by positive inhalation results. It is suggested that the intraperitoneal test can be used to exonerate a dust or fiber (because if negative in the intraperitoneal test it is extremely unlikely to be positive in either inhalation or intratracheal tests) but should not be used to positively determine that a dust or fiber is carcinogenic by inhalation. We would argue against the use of intraperitoneal tests for human health risk assessment except perhaps for the purpose of exoneration of a material from classification as a carcinogen.

This article considered the relationship between IP and inhalation results for several fibers, including RCF. For RCF, the authors noted that the RCC animal inhalation studies that resulted in fibrosis and tumors might have been compromised by the presence of non-representative amounts of particulate material, a point made in several earlier articles (Brown et al., 2005).

## Concluding comments

Several useful and informative publications have appeared since the Utell & Maxim (2010) review. Based on these and the earlier studies, we conclude:

- Correctly interpreting the animal bioassay data is difficult because of uncertainties in correcting for or otherwise accounting for the possible effects of lung overload. Published risk estimates based on extrapolation of animal data span a wide range of unknown accuracy.
- The results of epidemiology studies (particularly the UC study) continue to support the conclusion that present RCF occupational exposures are unlikely to result in material decrements in lung function, interstitial fibrosis, incremental lung cancer or mesothelioma in the exposed population. The latest UC results confirm an elevated urinary cancer SMR in the occupationally exposed cohort, which UC investigators thought might be accounted for by smoking or other occupational exposures. The finding of an elevated leukemia SMR (without evidence of an exposure–response relation) is probably unrelated to RCF exposure and more likely related to other occupational exposures or lifestyle factors. The finding of an unconfirmed death from mesothelioma is probably the result of prior self-reported asbestos exposure and a work history of jobs for which occupational asbestos exposure is likely. Nonetheless, continued follow-up of the RCF-exposed cohort is important to learn more about possible linkages between RCF exposure and kidney and/or bladder disease, leukemia, and maintaining vigilance for mesothelioma given its long latency and relative infrequency in the population.
- Product stewardship efforts have been successful in substantially reducing occupational exposures to RCF (and other fibers) and will be continued at both production and end-user facilities. Workers who joined the cohort in recent years have substantially lower exposures compared to those who were initially exposed during the 1980s or earlier.
- The medical surveillance component of the stewardship program may provide indications of morbidity in the cohort not captured in the earlier UC morbidity studies or the ongoing UC mortality study.
- The ongoing mortality study provides useful data and, as the cohort ages and the time since first exposure of the worker's increases should yield yet more powerful data on long-latency outcomes.

- Finally, even though epidemiological findings indicate that present RCF occupational exposures are unlikely to result in adverse health outcomes, it is prudent to continue efforts to reduce RCF exposures and to develop efficient high temperature insulating wools with yet lower biopersistence and greater diameters to reduce the respirable fraction.

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## Disclosure statement

The authors performed this work as independent consultants. Both authors serve as consultants on a scientific review board for Unifrax, a major producer of HTIWs and have performed studies for the HTIW Coalition. Neither author has appeared in any legal or regulatory proceeding relative to RCF. The findings and conclusions are those of the authors alone and do not necessarily represent the views of the sponsor.

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## References

Adams RM. (1990). Dermatitis due to fibrous glass. In: Adams RM (ed.) Occupational skin disease. 2nd ed. Philadelphia: WB Saunders Company, 16–7.

Adegoke OJ, Blair A, Shu XO, et al. (2003). Occupational history and exposure and the risk of adult leukemia in Shanghai. Ann Epidemiol 13:485–94.

Agence Française de Sécurité Sanitaire de L'environment et du Travail (AFSSET). (2007). Les fibres minérales artificielles, évaluation de l'exposition de la population générale et des travailleurs. Saisine 2004/012 Rapport Final Relatif aux Fibres. April 2007. Paris: AFFSET, 290 p. Available from: https://www.anses.fr/fr/system/files/AIR2004et0012Ra.pdf [last accessed 19 Apr 2017].

Agency for Toxic Substances and Disease Registry (ATSDR). 2004. Toxicological Profile for Synthetic Vitreous Fibers. September 2004. Atlanta, GA: ATSDR. 332 p. Available from: https://www.atsdr.cdc.gov/ToxProfiles/tp161.pdf [last accessed 19 Apr 2017].

Aguilar-Madrid G, Robles-Pérez E, Juárez-Pérez CA, et al. (2010). Case-control study of pleural mesothelioma in workers with social security in Mexico. Am J Ind Med 53:241–51.

Aidan JC, Priddee NR, McAleer JJ. (2013). Chemotherapy causes cancer! A case report of therapy related acute myeloid leukaemia in early stage breast cancer. Ulster Med J 82:97–9.

Anderson AS, Key TJ, Norat T, et al. (2015). European code against cancer 4th edition: obesity, body fatness and cancer. Cancer Epidemiol 39(Suppl 1):S34–S45.

Andujar P, Lacourt A, Brochard P, et al. (2016). Five years update on relationships between malignant pleural mesothelioma and exposure to asbestos and other elongated mineral particles. J Toxicol Environ Health Part B 19:151–72.

Anonymous. (1979). Asbestos, the insulation that lingers. All Hands, Magazine of the U.S. Navy, No. 755:6–11. Available from: http://www.navy.mil/ah_online/archpdf/ah197912.pdf [last accessed 10 July 2017].

Band PR, Le ND, Fang R, et al. (1996). Cohort study of Air Canada pilots: mortality, cancer incidence, and leukemia risk. Am J Epidemiol 143:137–43.

Baris D, Karagas MR, Verrill C, et al. (2009). A case-control study of smoking and bladder cancer risk: emergent patterns over time. J Natl Cancer Inst 101:1553–61.

Battista G, Belli S, Combat P, et al. (1999). Mortality due to asbestos-related causes among railway carriage construction and repair workers. Occup Med 49:536–9.

Behrman AJ. (2003). Welders and Joiners. In: Greenberg MI, editor. Occupational, industrial, and environmental toxicology. 2nd ed. Philadelphia, PA: Mosby; p. 398–405.

Bellmann B, Muhle H, Creutzenberg O, et al. (2001). Effects of nonfibrous particles on ceramic fiber (RCF1) toxicity in rats. Inhal Toxicol 13:101–25.

Bernstein DM. (2007). Synthetic vitreous fibers: a review toxicology, epidemiology and regulations. Crit Rev Toxicol 37:839–86.

Bianchi C, Bianchi T. (2009). Malignant pleural mesothelioma in Italy. Indian J Occup Environ Med 13:80–3.

Bianchi C, Brollo A, Ramani L, et al. (2001). Asbestos exposure in malignant mesothelioma of the pleura: a survey of 557 cases. Ind Health 39:161–7.

Björnberg A. (1985). Glass fiber dermatitis. Am J Ind Med 8:395–400.

Boffetta P, Saracci R, Andersen A, et al. (1997). Cancer mortality among man-made vitreous fiber production workers. Epidemiology 8:259–68.

Boffetta P, Andersen A, Hansen J, et al. (1999). Cancer incidence among European man-made vitreous fiber production workers. Scand J Work Environ Health 25:222–6.

Boffetta P, Donaldson K, Moolgavkar S, Mandel JS. (2014). A systematic review of occupational exposure to synthetic vitreous fibers and mesothelioma. Crit Rev Toxicol 44:436–49.

Brown LM, Blair A, Gibson R, et al. (1990). Pesticide exposures and other agricultural risk factors for leukemia among men in Iowa and Minnesota. Cancer Res 50:6585–91.

Brown RC, Sébastien P, Bellmann B, Muhle H. (2000). Particle contamination in experimental fiber preparations. Inhal Toxicol 12:99–107.

Brown RC, Bellmann B, Muhle H, et al. (2005). Survey of the biological effects of refractory ceramic fibres: overload and its possible consequences. Ann Occup Hyg 49:295–307.

Brown RC, Harrison PTC. (2012). Alkaline earth silicate wools – a new generation of high temperature insulation. Regul Toxicol Pharm 64:296–304.

Brown T, Slack R, Rushton L, British Occupational Cancer Burden Study Group. (2012). Occupational cancer in Britain. Urinary tract cancers: bladder and kidney. Br J Cancer 107(S1):S76–S84.

Brownson RC, Chang JC, Davis JR. (1987). Occupation, smoking, and alcohol in the epidemiology of bladder cancer. Am J Public Health 77:1298–300.

Brownson RC, Novotny TE, Perry MC. (1993). Cigarette smoking and adult leukemia. A meta-analysis. Arch Intern Med 153:469–75.

Burge PS, Calvert IA, Trethowan WN, Harrington JM. (1995). Are the respiratory health effects found in manufacturers of ceramic fibers due to the dust rather than the exposure to fibers?. Occup Environ Med 52:105–9.

Burger M, Catto JWF, Dalbagni G, et al. (2013). Epidemiology and risk factors of urothelial bladder cancer. Eur Urol 63:234–41.

Burley CG, Brown RC, Maxim LD. (1997). Refractory ceramic fibres: the measurement and control of exposure. Ann Occup Hyg 41, Supplement 1:267–72.

Butnor KJ, Sporn TA, Roggli VL. (2003). Exposure to brake dust and malignant mesothelioma: a study of 10 cases with mineral fiber analyses. Ann Occup Hyg 47:325–30.

Calle EE, Rodriguez C, Walker-Thurmond K, Thun MJ. (2003). Overweight, obesity, and mortality from cancer in a prospectively studied cohort of US adults. N Engl J Med 348:1625–38.

Carel R, Olsson AC, Zaridze D, et al. (2007). Occupational exposure to asbestos and man-made vitreous fibres and risk of lung cancer: a multicentre case-control study in Europe. Occup Environ Med 64:502–8.

Carlsten C, Georas SN. (2014). Update in Environmental and Occupational Lung Diseases 2013. Am J Respir Crit Care Med 89:1037–43.

Castleman B, Camarota LA, Fritsch AJ, et al. (1975). The hazards of asbestos for brake mechanics. Public Health Rep 90:254–6.

Cassidy A, Wang W, Wu X, Lin J. (2009). Risk of urinary bladder cancer: a case-control analysis of industry and occupation. BMC Cancer 9:443–51.

Castillo JJ, Reagan JL, Ingham RR, et al. (2012). Obesity but not overweight increases the incidence and mortality of leukemia in adults: a meta-analysis of prospective cohort studies. Leuk Res 36:868–75.

Chang C-H, Wang C-M, Ho C-K, et al. (1996). Fiberglass dermatitis: a case report. Kaohsiung J Med Sci 12:491–4.

Chiazze L, Watkins DK, Fryar C. (1997). Historical cohort mortality study of a continuous filament fiberglass manufacturing plant. I. White Men. J Occup Environ Med 39:432–41.

Chiazze L, Watkins DK, Fryar C, et al. (1999). Mortality from nephritis and nephrosis in the fiberglass manufacturing industry. Occup Environ Med 56:164–6.

Chinushi M, Koyama S, Takahashi M, et al. (1990). The occurrence of leukemia in a patient with pulmonary asbestosis. Jpn J Med 29:607–10.

Chiu WA, Jinot J, Scott CS, et al. (2013). Human health effects of trichloroethylene: key findings and scientific issues. Environ Health Perspect 121:303–11.

Chow W-H, Devesa SS. (2008). Contemporary epidemiology of renal cell cancer. Cancer J 14:288–301.

Chow W-H, Dong LM, Devesa SS. (2010). Epidemiology and risk factors for kidney cancer. Nat Rev. Urology 7:245–57.

Chow W-H, Gridley G, Fraumeni JF, Järvholm B. (2000). Obesity, hypertension, and the risk of kidney cancer in men. N Engl J Med 343:1305–11.

Clapp RW, Jacobs MM, Loechler EL. (2008). Environmental and occupational causes of cancer: new evidence 2005-2007. Rev Environ Health 23:1–37.

Clarke CC, Mowat FS, Kelsh MA, Roberts MA. (2006). Pleural plaques: a review of diagnostic issues and possible nonasbestos factors. Arch Environ Occup Health 61:183–92.

Claude J, Frentzel-Beyme R. (1984). A mortality study of workers employed in a German rock wool factory. Scand J Work, Environ Health 10:151–7.

Collins JJ, Lineker GA. (2004). A review and meta-analysis of formaldehyde exposure and leukemia. Regul Toxicol Pharmacol 40:81–91.

Costantini AS, Benvenuti A, Vineis P, et al. (2008). Risk of leukemia and multiple myeloma associated with exposure to benzene and other organic solvents: evidence from the Italian Multicenter Case-control study. Am J Ind Med 51:803–11.

Costa R, Orriols R. (2012). Man-made mineral fibers and the respiratory tract. Arch Bronconeumol 48:460–8.

Cowie HA, Wild P, Beck J, et al. (2001). An epidemiological study of the respiratory health of workers in the European refractory ceramic fiber (RCF) industry. Occup Environ Med 58:800–10.

Curtis RE, Boice JD, Jr, Stovall M, et al. (1992). Risk of leukemia after chemotherapy and radiation treatment for breast cancer. New Engl J Med 326:1745–51.

Danaei G, Vander Hoorn S, Lopez AD, et al. (2005). Causes of cancer in the world: comparative risk assessment of nine behavioural and environmental risk factors. Lancet 366:1784–93.

Davis JMG, Addison J, Bolton RE, et al. (1984). The pathogenic effects of fibrous ceramic aluminium silicate glass administered to rats by inhalation or peritoneal injection. In Biological Effects of Man-made Mineral Fibres. Proceedings of a Symposium 1982. Copenhagen: World Health Organisation, 303–22.

DECOS. (2011). Refractory Ceramic Fibres; Evaluation of the Carcinogenicity and Genotoxicity. Dutch Expert Committee on Occupational Safety. The Hague: Health Council of the Netherlands. Publication no. 2011/29.

De Roos AJ, Martínez-Maza O, Jerome KR, et al. (2013). Investigation of Epstein-Barr virus as a potential cause of B-cell non-Hodgkin lymphoma in a prospective cohort. Cancer Epidemiol Biomarkers Prev 22:1747–55.

Deschler B, Lübbert M. (2006). Acute myeloid leukemia: epidemiology and etiology. Cancer 107:2099–107.

Dotson GS. (2006). Characterization of asbestos exposure among automotive mechanics servicing and handling asbestos-containing materials. PhD Thesis, Department of Environmental and Occupational Health College of Public Health University of South Florida.

Drummond G, Bevan R, Harrison P. (2016). A comparison of the results from intra-pleural and intra-peritoneal studies with those from inhalation and intratracheal tests for the assessment of pulmonary responses to inhalable dusts and fibres. Regul Toxicol Pharm 81:89–105.

Egilman D, Billings MA. (2005). Abuse of epidemiology: automobile manufacturers manufacture a defense to asbestos liability. Int J Occup Environ Health 11:360–71.

Egilman D, Longo WE. (2012). Egilman's assessment rewarding exposures of auto mechanics to amphiboles is correct. Inhal Toxicol 24:614–8.

Environmental Resources Management (ERM). 1995. Description and characterization of the ceramic fibres industry of the European Union (Reference 3059). ERM is a trading name of ERL, Environmental Resources Limited. Brussels, Belgium: Environmental Resources Management (ERM).

Eun HC, Lee HG, Paik NW. (1991). Patch test responses to rockwool of different diameters evaluated by cutaneous blood flow measurement. Contact Dermatitis 24:270–3.

Everest Consulting Associates, Cranbury, NJ. (1996). Refractory ceramic fibers: a substitute study. Washington, DC: Refractory Ceramic Fibers Coalition (RCFC).

Everest Consulting Associates, Princeton Junction, NJ. (2017). PSP 2012: a voluntary product stewardship program (PSP), 2016 Annual Report by HTIW Coalition to the Occupational Safety and Health Administration (OSHA) Complete Edition. Washington, DC: HTIW Coalition.

Fernberg P, Odenbro Å, Bellocco R, et al. (2007). Tobacco use, body mass index, and the risk of leukemia and multiple myeloma: a nationwide cohort study in Sweden. Cancer Res 67:5983–6.

Finkelstein MM. (2008). Asbestos fibre concentrations in the lungs of brake workers: another look. Ann Occup Hyg 52:455–61.

Finley BL, Pierce JS, Paustenbach DJ, et al. (2012). Malignant pleural mesothelioma in US automotive mechanics: reported vs expected number of cases from 1975 to 2007. Regul Toxicol Pharmacol 64:104–16.

Fircanis S, Merriam P, Khan N, Castillo JJ. (2014). The relation between cigarette smoking and risk of acute myeloid leukemia: an updated meta-analysis of epidemiological studies. Am J Hematology 89:E125–32.

Floderus B, Persson T, Stenlund C, et al. (1993). Occupational exposure to electromagnetic fields in relation to leukemia and brain tumors: a case-control study in Sweden. Cancer Causes Control 4:465–76.

Franke K, Paustenbach D. (2011). Government and Navy knowledge regarding health hazards of asbestos: a state of the science evaluation (1900 to 1970). Inhal Toxicol 23 Suppl 3:1–20.

Freeman MD, Kohles SS. (2012). Assessing specific causation of mesothelioma following exposure to chrysotile asbestos-containing brake dust. Int J Occup Environ Health 18:329–36.

Freedman ND, Silverman DT, Hollenbeck AR, et al. (2011). Association between smoking and risk of bladder cancer among men and women. J Am Med Assoc 306:737–45.

Garabrant DH, Alexander DD, Miller PE, et al. (2016). Mesothelioma among motor vehicle mechanics: an updated review and meta-analysis. Ann Occup Hyg 60: 8–26.

Garshick E, Schenker MB, Woskie SR, Speizer FE. (1987). Past exposure to asbestos among active railroad workers. Am J Ind Med 12:399–406.

Gasparrini A, Pizzo AM, Gorini G, et al. (2008). Prediction of mesothelioma and lung cancer in a cohort of asbestos exposed workers. Eur J Epidemiol 23:541–6.

Gérazime A, Stücker I, Luce D. (2015). Exposition professionnelle aux fibres céramiques réfractaires et cancers respiratoires: résultats de l'étude Icare. Arch Maladies Profess L'Environ 76:399.

Gerosa A, Ietri E, Belli S, et al. (2000). High risk of pleural mesothelioma among the state railroad carriage repair workers. Epidemiol Prev 24:117–9.

Ghadimi T, Gheitasi B, Nili S, et al. (2015). Occupation, smoking, opium, and bladder cancer: a case-control study. South Asian J Cancer 4:111–4.

Glass DC, Gray CN, Jolley DJ, et al. (2003). Leukemia risk associated with low-level benzene exposure. Epidemiology 14:569–77.

Goldsmith JR, Goldsmith DF. (1993). Fiberglass or silica exposure and increased nephritis or ESRD (end-stage renal disease). Am J Ind Med 28:873–81.

Golka K, Goebell PJ, Rettenmeier AW. (2007). Bladder cancer: etiology and prevention. Deutsches Ärzteblatt 104:719–23.

Golka K, Wiese A, Assennato G, Bolt HM. (2004). Occupational exposure and urological cancer. World J Urol 21:382–91.

González CA, López-Abente G, Errezola M, et al. (1989). Occupation and bladder cancer in Spain: a multi-centre case-control study. Int J Epidemiol 18:569–77.

Goodman M, Morgan RW, Ray R, et al. (1999). Cancer in asbestos-exposed occupational cohorts: a meta-analysis. Cancer Causes Control 10:453–65.

Goodman M, Teta MJ, Hessel PA, et al. (2004). Mesothelioma and lung cancer among motor vehicle mechanics: a meta-analysis. Ann Occup Hyg 48:309–26.

Greaves MF. (1997). Aetiology of acute leukaemia. Lancet 349:344–9.

Greenberg M. (1991). Cancer mortality in merchant seamen. Ann N Y Acad Sci 643:321–32.

Greim H, Utell MJ, Maxim LD, Niebo R. (2014). Perspectives on refractory ceramic fiber (RCF) carcinogenicity: comparisons with other fibers. Inhal Toxicol 26:789–810.

Gross P, Westrick ML, Schrenk HH, McNerney JM. (1956). The effects of synthetic ceramic fiber dust upon the lungs of rats. AMA Arch Indust Health 13:161–6.

Gustavsson P, Plato N, Axelson O, et al. (1992). Lung cancer risk among workers exposed to man-made mineral fibers (MMMF) in the Swedish prefabricated house industry. Am J Ind Med 21:825–34.

Hansen ES. (1989). Mortality of auto mechanics. A ten-year follow-up. Scand J Work Environ Health 15:43–6.

Harling M, Schablon A, Schedlbauer G, et al. (2010). Bladder cancer among hairdressers: a meta-analysis. Occup Environ Med 67:351–8.

Harries PG. (1968). Asbestos hazards in naval dockyards. Ann Occup Hyg 11:135–45.

Harrison P, Holmes P, Bevan R, et al. (2015). Regulatory risk assessment approaches for synthetic mineral fibres. Regul Toxicol Pharm 43:425–41.,

Health and Safety Executive (HSE), (2008). Hazards from the use of Refractory Ceramic Fibre, Report OC 267/3. Suffolk, United Kingdom: HSE, 15 p. Available from: http://www.hse.gov.uk/foi/internalops/ocs/200-299/267_3v2.htm [last accessed 19 Dec 2016].

Heck JE, Charbotel B, Moore LE, et al. (2010). Occupation and renal cell cancer in Central and Eastern Europe. *Occup*. Environ Med 67:47–53.

Heck HDA, Casanova M. (2004). The implausibility of leukemia induction by formaldehyde: a critical review of the biological evidence on distant-site toxicity. Regul Toxicol Pharm 40:92–106.

Heisel EB, Hunt FE. (1968). Further studies in cutaneous reactions to glass fibers. Arch Environ Health 17:705–11.

Henshaw DL, Eatough JP, Richardson RB. (1990). Radon as a causative factor in induction of myeloid leukaemia and other cancers. Lancet 335:1008–12.

Hemelt M, Yamamoto H, Cheng KK, Zeegers MPA. (2009). The effect of smoking on the male excess of bladder cancer: a meta-analysis and geographical analyses. Int J Cancer 124:412–9.

Hessel PA, Teta MJ, Goodman M, Lau E. (2004). Mesothelioma among brake mechanics: an expanded analysis of a case-control study. Risk Anal 24:547–52.

Hesterberg TW, Chase G, Axten C, et al. (1998). Biopersistence of synthetic vitreous fibers and amosite asbestos in the rat lung following inhalation. Toxicol Appl Pharmacol 151:262–75.

Hesterberg TW, Hart GA. (2001). Synthetic vitreous fibers: a review of toxicology research and its impact on hazard classification. Crit Rev Toxicol 31:1–53.

Hill AB. (1965). The environment and disease: association or causation? Proc R Soc Med 58:295–300.

Hjortsberg U, Orbeak P, Arborelius M, et al. (1988). Railroad workers with pleural plaques: 1. spirometric and nitrogen washout investigation on smoking and nonsmoking asbestos-exposed workers. Am J Ind Med 14:635–41.

Hoffmann S, de Vries RB, Stephens ML, et al. (2017). A primer on systematic reviews in toxicology. Arch Toxicol 91:2551–75.

Hosoda Y, Hiraga Y, Sasagawa S. (2008). Railways and Asbestos in Japan (1928-1987)-epidemiology of pleural plaques, malignancies and pneumoconioses-. J Occup Health 50:297–307.

Hsieh MY, Guo YL, Shiao JS, Sheu HM. (2001). Morphology of glass fibers in electronics workers with fiberglass dermatitis–scanning electron microscopy study. Int J Dermatol 40:258–61.

Hu J, Mao Y, White K. (2002). Renal cell carcinoma and occupational exposure to chemicals in Canada. Occup Med (Lond) 52:157–64.

Huncharek M. (1987). Asbestos-related mesothelioma risk among railroad workers. Am Rev Respir Dis 135: 983–4.

Huncharek M. (1990). Brake mechanics, asbestos, and disease risk. Am J Forensic Med Pathol 11:236–40.

Huncharek M. (1992). Changing risk groups for malignant mesothelioma. Cancer 69:2704–11.

Hunt JD, van der Hel OL, McMillan GP, et al. (2005). Renal cell carcinoma in relation to cigarette smoking: meta-analysis of 24 studies. Int J Cancer 114:101–8.

Imbernon E, Marchand JL, Garras L, Goldberg M. (2005). Quantitative assessment of the risk of lung cancer and pleural mesothelioma among automobile mechanics. Rev D'epidemiol Sante Publique 53:491–500.

Industrial Injuries Advisory Council [IIAC]. (2008). Position Paper 23 – Pleural Plaques. London, UK: IIAC. 60 p. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328553/iiac-pp23.pdf [last accessed 10 Apr 2017].

Institute National de la Santé et de la Recherche Médicale (INSERM), (1999). Chapter 5 - Effets sur la santé humaine – Dermatoses induites par les fibres artificielles. Fibres de substitution à l'amiante. Rapport. Paris: Les editions, 247–65. Available from: http://www.ipubli.inserm.fr/bitstream/handle/10608/192/?sequence = 10.

International Agency for Research on Cancer (IARC). 2002. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 81, Man-Made Vitreous Fibres. Lyon, France: IARC. 433 p. Available from: https://monographs.iarc.fr/ENG/Monographs/vol81/mono81.pdf [last accessed 10 Apr 2017].

International Agency for Research on Cancer (IARC). (2012). Chemical agents and related occupations, volume 100 F, A review of human carcinogens. Lyon, France: IARC.

International Agency for Research on Cancer (IARC). (2004). IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. Tobacco smoke and involuntary smoking. IARC Working Group On The Evaluation Of Carcinogenic Risks To Humans. Lyon, France: IARC. 1476 p. Available from: https://monographs.iarc.fr/ENG/Monographs/vol83/mono83.pdf [last accessed 10 Apr 2017].

Iwatsubo Y, Pairon JC, Boutin C, et al. (1998). Pleural mesothelioma: dose-response relation at low levels of asbestos exposure in a French population-based case-control study. Am J Epidemiol 148:133–42.

Janout V, Janoutova G. (2004). Epidemiology and risk factors of kidney cancer. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub 148:95–101.

Jolanki R, Mäkinen I, Suuronen K, et al. (2002). Occupational irritant contact dermatitis from synthetic mineral fibres according to Finnish statistics. Contact Dermatitis 47:329–33.

Kakooei H, Hormozy M, Marioryad H. (2011). Evaluation of asbestos exposure during brake repair and replacement. Ind Health 49:374–80.

Kane EV, Roman E, Cartwright R, et al. (1999). Tobacco and the risk of acute leukaemia in adults. Br J Cancer 81:1228–33.

Kanerva L, Wahlberg JE, Elsner P, Maibach HI (eds.). (2013). Handbook of occupational dermatology. Berlin, Heidelberg: Springer. 1300 p.

Kannio A, Ridanpää M, Koskinen H, et al. (1996). A molecular and epidemiological study on bladder cancer: p53 mutations, tobacco smoking, and occupational exposure to asbestos. Cancer Epidemiol Biomarkers Prev 5:33–9.

Karakosta M, Delicha EM, Kouraklis G, Manola KN. (2016). Association of various risk factors with chronic lymphocytic leukemia and its cytogenetic characteristics. Arch Environ Occup Health 71:317–29.

Karami S, Boffetta P, Stewart PS, et al. (2011). Occupational exposure to dusts and risk of renal cell carcinoma. Br J Cancer 104:1797–803.

Karami S, Colt JS, Schwartz K, et al. (2012). A case-control study of occupation/industry and renal cell carcinoma risk. BMC Cancer 12:344.

Kerper LE, Lynch HN, Zu K, et al. (2015). Systematic review of pleural plaques and lung function. Inhal Toxicol 27:15–44.

Khoubi J, Pourabdian S, Mohebbi I, et al. (2013). Association between the high risk occupations and bladder cancer in Iran: a case-control study. Int J Occup Med Environ Health 26:205–13.

Kieć-Świerczyńska M, Wojtczak J. (2000). Occupational ceramic fibres dermatitis in Poland. Occup Med (Lond) 50:337–42.

Kieć-Świerczyńska M, Szymczk W. (1995). The effect of the working environment on occupational skin disease development in workers processing rockwool. Int J Occup Med Environ Health 8:17–22.

Kim I, Ha J, Lee J-H, et al. (2014). The relationship between the occupational exposure of trichloroethylene and kidney cancer. Ann Occup Environ Med 26:12.

Kishimoto T, Ono T, Okada K. (1988). Acute myelocytic leukemia after exposure to asbestos. Cancer 62:787–90.

Kishimoto T. (1992). Cancer due to asbestos exposure. Chest 101:58–63.

Koebnick C, Michaud D, Moore SC, et al. (2008). Body mass index, physical activity, and bladder cancer in a large prospective study. Cancer Epidemiol Biomarkers Prev 17:1214–21.

Kogevinas M, Mannetje A, Cordier S, et al. (2003). Occupation and bladder cancer among men in Western Europe. Cancer Causes Control 14:907–14.

Koh D, Aw TC, Foulds IS. (1992). Fiberglass dermatitis from printed circuit boards. Am J Ind Med 21:193–8.

Konzen JL. (1987). Fiberglass and the skin. In: Maibach HI (ed.) Occupational and industrial dermatology, 2nd ed. Chicago: Yearbook Medical Publishers,283–5.

Kurumatani N, Natori Y, Mizutani R, et al. (1999). A historical cohort mortality study of workers exposed to asbestos in a refitting shipyard. Ind Health 37:9–17.

Lachapelle JM. (2006). Chapter 8: irritant dermatitis. In: Chew A-L, HI Maibach (eds.) Airborne irritant dermatitis. Berlin: Springer, 71–9.

Lachapelle JM. (1986). Industrial airborne irritant or allergic contact dermatitis. Contact Dermatitis 3:137–45.

Lacourt A, Gramond C, Audignon S, et al. (2013). Pleural mesothelioma and occupational coexposure to asbestos, mineral wool, and silica. Am J Respir Crit Care Med 187:977–82.

Lacourt A, Rinaldo M, Gramond C, et al. (2014). Co-exposure to refractory ceramic fibres and asbestos and risk of pleural mesothelioma. Eur Respir J 44:725–33.

Laden F, Stampfer MJ, Walker AM. (2004). Lung cancer and mesothelioma among male automobile mechanics: a review. Rev Environ Health 19:39–61.

Lauriola M, Bua L, Chiozzotto D, et al. (2012). Urinary apparatus tumours and asbestos: the Ramazzini Institute caseload. Arch Ital Urol Androl 84:189–96.

Larsson SC, Wolk A. (2008). Overweight and obesity and incidence of leukemia: a meta-analysis of cohort studies. Int J Cancer 122:1418–21.

Lee TV, Lam TH. (1992). Occupational fiberglass dermatitis in Hong Kong. Contact Dermatitis 27:341–3.

LeMasters GK, Lockey JE, Levin LS, et al. (1998). An industry-wide pulmonary study of men and women manufacturing refractory ceramic fibers. Am J Epidemiol 148:910–9.

LeMasters GK, Lockey JE, Yiin JH, et al. (2003). Mortality of workers occupationally exposed to refractory ceramic fibers. J Occup Environ Med 45:440–50.

LeMasters GK, Lockey JE, Hilbert TJ, et al. (2017). A thirty-year mortality and respiratory morbidity study of Refractory Ceramic Fiber workers. Inhal. Toxicol 29: 462–70.

Lemen RA. (2004). Asbestos in brakes: exposure and risk of disease. Am J Ind Med 45:229–37.

Leuraud K, Richardson DB, Cardis E, et al. (2015). Ionising radiation and risk of death from leukaemia and lymphoma in radiation-monitored workers (INWORKS): an international cohort study. Lancet Haematol 2:e276–81.

Lewis JD, Ferrara A, Peng T, et al. (2011). Risk of bladder cancer among diabetic patients treated with pioglitazone: interim report of a longitudinal cohort study. Diabetes Care 34:916–22.

Lippmann M. (2014). Toxicological and epidemiological studies on effects of airborne fibers: coherence and public health implications. Crit Rev Toxicol 44:643–95.

Lipworth L, Tarone RE, Lund L, McLaughlin JK. (2009). Epidemiologic characteristics and risk factors for renal cell cancer. Clin Epidemiol 1:33–43.

Ljungberg B, Campbell SC, Cho HY, et al. (2011). The epidemiology of renal cell carcinoma. Eur Urol 60:615–21.

Lockey J, LeMasters G, Rice C, et al. (1996). Refractory ceramic fiber exposure and pleural plaques. Am J Respir Crit Care Med 154:1405–10.

Lockey JE, Levin LS, LeMasters GK, et al. (1998). Longitudinal estimates of pulmonary function in refractory ceramic fiber manufacturing workers. Am J Respir Crit Care Med 157:1226–33.

Lockey JE, LeMasters GK, Levin LS, et al. (2002). A longitudinal study of chest radiographic changes of workers in the refractory ceramic fiber industry. Chest 121:2044–51.

Lockey JE, Roggli VL, Hilbert TJ, et al. (2012). Biopersistence of refractory ceramic fiber in human lung tissue and a 20-year follow-up of radiographic pleural changes in workers. J Occup Environ Med 54:781–8.

Lundgren L, Moberg C, Lidén C. (2014). Do insulation products of man-made vitreous fibres still cause skin discomfort? Contact Dermatitis 70:351–60.

Lynge E, Andersen A, Rylander L, et al. (2006). Cancer in persons working in dry cleaning in the Nordic countries. Environ Health Perspect 114:213–9.

Malker HS, McLaughlin JK, Malker BK, et al. (1985). Occupational risks for pleural mesothelioma in Sweden, 1961-79. J Natl Cancer Inst 74:61–6.

Maltoni C, Pinto C, Carnuccio R, et al. (1995). Mesotheliomas following exposure to asbestos used in railroads: 130 Italian cases. Med Lav 86:461–77.

Mancuso TF. (1983). Mesothelioma among machinists in railroad and other industries. Am J Ind Med 4:501–13.

Mancuso TF. (1988). Relative risk of mesothelioma among railroad machinists exposed to chrysotile. Am J Ind Med 13: 639–57.

Mancuso TF. (1991). Mesotheliomas among railroad workers in the United States. Ann N Y Acad Sci 643:333–46.

Mangold CA, Beckett RR, Bessmer DJ. (1970). Asbestos exposure and control at Puget Sound Naval Shipyard. Bremerton, WA: Industrial Hygiene Division Medical Department, Puget Sound Naval Shipyard.

Marchand JL, Luce D, Leclerc A, et al. (2000). Laryngeal and hypopharyngeal cancer and occupational exposure to asbestos and man-made vitreous fibers: results of a case-control study. Am J Ind Med 37:581–9.

Mariusdottir E, Ingimarsson JP, Jonsson E, et al. (2016). Occupation as a risk factor for renal cell cancer: a nationwide, prospective epidemiological study. Scand J Urol 50:181–5.

Marsh GM, Enterline PE, Stone RA, Henderson VL. (1990). Mortality among a cohort of US man-made mineral fiber workers: 1985 follow-up. J Occup Med 32:594–604.

Marsh G, Stone R, Youk A, et al. (1996). Mortality among United States rock wool and slag wool workers: 1989 update. J Occup Health Saf Aust NZ 12:297–312.

Marsh GM, Youk AO, Stone RA, et al. (2001a). Historical cohort study of US man-made vitreous fiber production workers: I. 1992 fiberglass cohort follow-up: initial findings. J Occup Environ Med 43:741–56.

Marsh GM, Gula MJ, Youk AO, et al. (2001b). Historical cohort study of US man-made vitreous fiber production workers: II. Mortality from mesothelioma. J Occup Environ Med 43:757–66.

Mast RW, McConnell EE, Anderson R, et al. (1995b). Studies on the chronic toxicity (inhalation) of four types of refractory ceramic fiber in male Fischer 344 rats. Inhal Toxicol 7:425–67.

Mast RW, McConnell EE, Hesterberg TW, et al. (1995a). Multiple-dose chronic inhalation toxicity study of size-separated kaolin refractory ceramic fiber in male Fischer 344 rats. Inhal Toxicol 7:469–502.

Mast RW, Maxim LD, Utell MJ, Walker AM. (2000a). Refractory ceramic fiber: toxicology, epidemiology, and risk analyses – a review. Inhal Toxicol 12:359–99.

Mast RW, Yu CP, Oberdörster G, et al. (2000b). A retrospective review of the carcinogenicity of refractory ceramic fiber in two chronic Fischer 344 rat inhalation studies: an assessment of the MTD and implications for risk assessment. Inhal Toxicol 12:1141–72.

Matsuoka M, Jeang KT. (2007). Human T-cell leukaemia virus type 1 (HTLV-1) infectivity and cellular transformation. Nat Rev Cancer 7:270–80.

Matsuzaki H, Lee S, Kumagai-Takei N, et al. (2015). Biological effects of refractory ceramic fiber. Kawasaki Med J 41:57–63.

Maxim LD, Allshouse JN, Chen SH, et al. (2000). Workplace monitoring of refractory ceramic fiber in the United States. Regul Toxicol Pharm 32:293–309.,

Maxim LD, Allshouse JN, Deadman J, et al. (1998). CARE: a European programme for monitoring and reducing refractory ceramic fibre dust at the workplace: initial results. Gefahrstoffe-Reinhaltung Der Luft 58:97–103.

Maxim LD, Allshouse J, Fairfax RF, et al. (2008). Workplace monitoring of occupational exposure to refractory ceramic fiber – a 17-year retrospective. Inhal Toxicol 20:289–309.

Maxim LD, Allshouse JN, Kelly WP, et al. (1997). A multiyear workplace-monitoring program for refractory ceramic fibers: findings and conclusions. Regul Toxicol Pharmacol 26:156–71.

Maxim LD, Hadley JG, Potter RM, Niebo R. (2006). The role of fiber durability/biopersistence of silica-based synthetic vitreous fibers and their influence on toxicology. Regul Toxicol Pharm 46:42–62.

Maxim LD, Kelly WP, Walters T, Waugh R. (1994). A multiyear workplace-monitoring program for refractory ceramic fibers. Regul Toxicol Pharmacol 20:S200–S15.

Maxim LD, Niebo R, Utell MJ. (2015). Are pleural plaques an appropriate endpoint for risk analyses? Inhal Toxicol 27:321–34.

Maxim LD, Yu CP, Oberdörster G, Utell MJ. (2003). Quantitative risk analyses for RCF: survey and synthesis. Regul Toxicol Pharmacol 38:400–16.

McConnell EE, Mast RW, Hesterberg TW, et al. (1995). Chronic inhalation toxicity of a kaolin based refractory ceramic fiber (RCF) in Syrian Golden hamsters. Inhal Toxicol 7:503–32.

McDonald C, McDonald A. (1989). Mesothelioma in railroad workers. Am J Ind Med 15:487–90.

McDonald TA, Holland NT, Skibola C, et al. (2001). Hypothesis: phenol and hydroquinone derived mainly from diet and gastrointestinal flora activity are causal factors in leukemia. Leukemia 15:10–20.

McKay RT, LeMasters GK, Hilbert TJ, et al. (2011). A long term study of pulmonary function among US refractory ceramic fibre workers. Occup Environ Med 68:89–95.

McLaughlin JK, Lipworth L, Tarone RE. (2006). Epidemiologic aspects of renal cell carcinoma. Semin Oncol 33:527–33.

Michaels D, Monforton C. (2007). How litigation shapes the scientific literature: asbestos and disease among automobile mechanics. J Law Policy 15:1137–70.

Minamoto K, Nagano M, Inaoka T, et al. (2002). Skin problems among fiber-glass reinforced plastics factory workers in Japan. Ind Health 40:42–50.

Morfeld P, Mundt KA, Dell LD, et al. (2016). Meta-analysis of cardiac mortality in three cohorts of carbon black production workers. Int J Environ Res Public Health 13:302–31.

Moolgavkar SH, Anderson EL, Chang ET, et al. (2014). A review and critique of U.S. EPA's risk assessments for asbestos. Crit Rev Toxicol 44:499–522.

Moore LE, Boffetta P, Karami S, et al. (2010). Occupational trichloroethylene exposure and renal carcinoma risk: evidence of genetic susceptibility by reductive metabolism gene variants. Cancer Res 70:6527–36.

Morinaga K, Nakamura K, Kohyama N, Kishimoto T. (1999). A retrospective cohort study of male workers exposed to PVA fibers. Ind Health 37:18–21.

Mostafa MH, Sheweita SA, O'Connor PJ. (1999). Relationship between schistosomiasis and bladder cancer. Clin Microbio Rev 12:97–111.

Moyad MA. (2001). Review of potential risk factors for kidney (renal cell) cancer. Semin Urol Oncol 19:280–93.

National Institute for Occupational Safety and Health (NIOSH). 2006. Criteria for a Recommended Standard Occupational Exposure to Refractory Ceramic Fibers. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control Prevention, National Institute for Occupational Safety and Health, 204 p.

National Research Council (NRC). 2000. Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers, Subcommittee on Manufactured Vitreous Fibers, Committee on Toxicology, Board on Environmental Studies and Toxicology, Commission on Life Sciences National Research Council. Wsshington, DC: National Academy Press. 73 p.

Ohlson C-G, Klaesson B, Hogstedt C. (1984). Mortality among asbestos-exposed workers in a railroad workshop. Scand J Work Environ Health 10:283–91.

Olfert SM, Felknor SA, Delclos GL. (2006). An updated review of the literature: risk factors for bladder cancer with focus on occupational exposures. Southern Med J 99:1256–63.

Oliver LC, Eisen EA, Greene RE, Sprince NL. (1985). Asbestos-related disease in railroad workers: a cross-sectional study. Am Rev Respir Dis 131:499–504.

Olsen JH, Jensen OM. (1987). Occupation and risk of cancer in Denmark. An analysis of 93,810 cancer cases, 1970-1979. Scand J Work Environ Health 13(Suppl 1):1–91.

Orth SR. (1997). The renal risks of smoking. Kidney Int 51:1669–7.

Partanen T, Heikkilä P, Hernberg S, et al. (1991). Renal cell cancer and occupational exposure to chemical agents. Scand J Work Environ Health 17:231–9.

Pascual D, Borque A. (2008). Epidemiology of kidney cancer. Adv Urol 5:1–7.

Patiwael JA, Wintzen M, Rustemeyer T, Bruynzeel DP. (2005). Airborne irritant contact dermatitis due to synthetic fibres from an air-conditioning filter. Contact Dermatitis 52:126–9.

Paustenbach DJ, White KR. (2012). Egilman's assessment regarding exposures of auto mechanics to amphiboles is not accurate. Inhal Toxicol 24:609–13.

Pesch B, Haerting J, Ranft U, et al. (2000). Occupational risk factors for renal cell carcinoma: agent-specific results from a case-control study in Germany. Int J Epidemiol 29:1014–24.

Petersen R, Sabroe S. (1991). Irritative symptoms and exposure to mineral wool. Am J Ind Med 20:113–22.

Peto J, Rake C, Gilham C, Hatch J. (2009). Occupational, domestic and environmental mesothelioma risks in Britain: a case-control study. Norwich: HSE Books, 76 p.

Plato N, Martinsen JI, Sparén P, et al. (2016). Occupation and mesothelioma in Sweden: updated incidence in men and women in the 27 years after the asbestos ban. Epidemiol Health 38: e2016039.

Plato N, Westerholm P, Gustavsson P, et al. (1995). Cancer incidence, mortality and exposure-response among Swedish man-made vitreous fiber production workers. Scand J Work Environ Health 21:353–61.

Polychronakis I, Dounias G, Makropoulos RE, Linos A. (2013). Work-related leukemia: a systematic review. J Occup Med Toxicol 8:14.
Possick PA, Gellin GA, Key MM. (1970). Fibrous glass dermatitis. Am Ind Hyg Assoc J 31:12–5.
Qayyum T, Oades G, Horgan P, et al. (2012). The epidemiology and risk factors for renal cancer. Curr Urol 6:169–74.
Qin Q, Xu X, Wang X, Zheng X-Y. (2013). Obesity and risk of bladder cancer: a meta-analysis of cohort studies. Asian Pacific J Cancer Prev 14:3117–21.
Rake C, Gilham C, Hatch J, et al. (2009). Occupational, domestic and environmental mesothelioma risks in the British population: a case-control study. Br J Cancer 100:1175–83.
Rauscher GH, Sandler DP, Poole C, et al. (2002). Family history of cancer and incidence of acute leukemia in adults. Am J Epid 156:517–26.
Reulen RC, Kellen E, Buntinx F, et al. (2008). A meta-analysis on the association between bladder cancer and occupation. Scand J Urol Nephrol 42(Suppl):64–78.
Richardson DB, Cardis E, Daniels RD, et al. (2015). Risk of cancer from occupational exposure to ionising radiation: retrospective cohort study of workers in France, the United Kingdom, and the United States (INWORKS). BMJ 351:h5359.
Richardson K, Band PR, Astrakianakis G, Le ND. (2007). Male bladder cancer risk and occupational exposure according to a job-exposure matrix – a case-control study in British Columbia, Canada. Scand J Work Environ Health 33:454–64.
Richter RO, Finley BL, Paustenbach DJ, et al. (2009). An evaluation of short-term exposures of brake mechanics to asbestos during automotive and truck brake cleaning and machining activities. J Expos Sci Environ Epidemiol 19:458–74.
Rinsky RA. (1989). Benzene and leukemia: an epidemiologic risk assessment. Environ Health Perspect 82:189–91.
Rödelsperger K, Jöckel KH, Pohlabeln H, et al. (2001). Asbestos and man-made vitreous fibers as risk factors for diffuse malignant mesothelioma: results from a German hospital-based case-control study. Am J Ind Med 39:262–75.
Rodriguez-Abreu D, Bordoni A, Zucca E. (2007). Epidemiology of hematological malignancies. Ann Oncol 18:i3–8.
Roelofs CR, Kernan GJ, Davis LK, et al. (2013). Mesothelioma and employment in Massachusetts: analysis of cancer registry data 1988-2003. Am J Ind Med 56:985–92.
Rogers A, Yeung P, Berry G, et al. (1997). Exposure and respiratory health of workers in the Australian refractory ceramic fibre production industry. Ann Occup Hyg 41(Suppl 1):261–6.
Roggli VL, Sharma A, Butnor KJ, et al. (2002). Malignant mesothelioma and occupational exposure to asbestos: a clinicopathological correlation of 1445 cases. Ultrastruct Pathol 26:55–65.
Rolland P, Gramond C, Lacourt A, PNSM Study Group, et al. (2010). Occupations and industries in France at high risk for pleural mesothelioma: a population-based case-control study (1998-2002). Am J Ind Med 53:1207–19.
Rom WN, Markowitz SB (eds.). (2004). Environmental and occupational medicine. 4th ed. Philadelphia: Wolters Kluwer, Lippincott Williams and Wilkins. 1884 p.
Ross JA, Kasum CM, Davies SM, et al. (2002). Diet and risk of leukemia in the Iowa Women's Health Study. Cancer Epidemiol Biomarkers Prev 11:777–81.
Rubagotti A, Martorana G, Boccardo FM. (2006). Epidemiology of kidney cancer. Eur Urol Suppl 5:558–65.
Rushworth DH. (2005). The navy and asbestos thermal insulation. Naval Eng J 17:35–48.
Russo P. (2012). End stage and chronic kidney disease: associations with renal cancer. Front Oncol 2:1–7.
Sali D, Boffetta P. (2000). Kidney cancer and occupational exposure to asbestos: a meta-analysis of occupational cohort studies. Cancer Causes Control 11:37–47.
Sali D, Boffetta P, Andersen A, et al. (1999). Non-neoplastic mortality of European workers who produce man-made vitreous fibers. Occup Environ Med 56:612–7.
Sankila R, Karjalainen S, Pukkala E, et al. (1990). Cancer risk among glass factory workers: an excess of lung cancer? Br J Ind Med 47:815–8.
Scarselli A, Scanno P, Marinaccio A, Iavicoli S. (2011). Bladder cancer and occupational exposure: estimating the workers potentially at risk in Italy. Ann Ist Super Sanitaà 47:200–6.
Schenker MB, Garshick E, Muñoz A, et al. (1986). A population-based case-control study of mesothelioma deaths among U.S. railroad workers. Am Rev Respir Dis 134:461–5.
Schwilk E, Zhang L, Smith MT, et al. (2010). Formaldehyde and leukemia: an updated meta-analysis and evaluation of bias. J Occup Environ Med 52:878–86.
Scientific Committee on Occupational Exposure Limits (SCOEL). (2011). Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic Fibres SCOEL/SUM/165. Brussels: European Commission- Employment, Social Affairs and Inclusion, 21 p.
Seidler A, Becker N, Nieters A, et al. (2010). Asbestos exposure and malignant lymphoma: a multicenter case–control study in Germany and Italy. Int Arch Occup Environ Health 83:563–70.
Selikoff IJ. (1990). Historical developments and perspectives in inorganic fiber toxicity in man. Environ Health Perspect 88:269–76.
Selikoff IJ, Hammond EC. (1978). Asbestos-associated disease in United States shipyards. CA Cancer J Clin 28:87–99.
Selikoff IJ, Lilis R, Levin G. (1990). Asbestotic radiological abnormalities among United States merchant marine seamen. Br J Ind Med 47:292–7.
Serra C, Kogevinas M, Silverman DT, et al. (2008). Work in the textile industry in Spain and bladder cancer. Occup Environ Med 65:552–9.
Sertoli A, Giorgini S, Farli M. (1992). Fiberglass dermatitis. Clin Dermatol 10:167–74.
Shannon H, Hayes M, Julian JA, Muir DCF. (1984). Mortality experience of glass fibre workers. Br J Ind Med 41:35–8.
Shannon H, Muir A, Haines T, Verma D. (2005). Mortality and cancer incidence in Ontario glass fiber workers. Occup Med 55:528–34.
Siemiatycki J, Richardson L, Gérin M, et al. (1986). Associations between several sites of cancer and nine organic dusts: results from a hypothesis-generating case-control study in Montreal, 1979-1983. Am J Epidemiol 123:235–49.
Silverman D, Devesa S, Moore L, Rothman N. (2006). Bladder cancer. In: Schottenfeld D, Fraumeni JJ (eds.) Cancer epidemiology and prevention, 3rd ed.). Chapter 58. New York, NY: Oxford University Press.
Sim MR, Echt A. (1996). An outbreak of pruritic skin lesions in a group of laboratory workers – a case report. Occup Med (Lond) 46:235–8.
Simonato L, Fletcher AC, Cherrie J, et al. (1986). The man-made mineral fiber European historical cohort study: extension of the follow-up. Scand J Work Environ Health 12:34–47.
Skotnicki-Grant S. (2008). Allergic Contact Dermatitis versus Irritant Contact Dermatitis. Discussion Paper prepared for Workplace Safety and Insurance Appeals Tribunal. Toronto: University of Toronto – Division of Dermatology and Occupational Health – St. Michael's Hospital. Available from: http://www.wsiat.on.ca/english/mlo/allergic.htm [last accessed 19 Apr 2017].
Smith DM, Ortiz LW, Archuleta RF, Johnson NF. (1987). Long term health effects in hamsters and rats exposed chronically to man-made vitreous fibers. Ann Occup Hyg 31:731–43.
Smith MT, Zhang L. (1998). Biomarkers of leukemia risk: benzene as a model. Environ Health Perspect 106(Suppl 4): 937–43.
Song X, Pukkala E, Dyba T, et al. (2014). Body mass index and cancer incidence: the FINRISK study. Eur J Epidemiol 29:477–87.
Spinelli J. (1989). Mortality and cancer incidence in workers at the Alcan aluminum plant in Kitimat, B.C.: final report. British Columbia: Cancer Control Agency of British Columbia.
Stam-Westerveld EB, Coenraads PJ, Van der Valk PGM, et al. (1994). Rubbing test responses of the skin to man-made mineral fibres of different diameters. Contact Dermatitis 31:1–4.

Stone RA, Youk AO, Marsh GM, et al. (2004). Historical cohort study of U.S. man-made vitreous fiber production workers IX: summary of 1992 mortality follow up and analysis of respiratory system cancer among female workers. J Occup Environ Med 46:55–67.

Strand L, Martinsen JI, Koefoed VF, et al. (2010). Asbestos-related cancers among 28,300 military servicemen in the Royal Norwegian Navy. Am J Ind Med 53:64–71.

Strom SS, Yamamura Y, Kantarijian HM, Cortes-Franco JE. (2009). Obesity, weight gain, and risk of chronic myeloid leukemia. Cancer Epidemiol Biomarkers Prev 18:1501–6.

Sun JW, Zhao LG, Yang Y, et al. (2015). Obesity and risk of bladder cancer: a dose-response meta-analysis of 15 cohort studies. PLoS One 10:1–11.

Tarvainen K, Estlander T, Jolanki R, Kanerva L. (1994). Occupational dermatoses caused by man-made mineral fibers. Dermatitis 5:22–9.

Teppo L, Kojonen E. (1986). Mortality and cancer risk among workers exposed to man-made mineral fibers in Finland. Scand J Work Environ Health 12:61–4.

Teschke K, Morgan MS, Checkoway H, et al. (1997). Mesothelioma surveillance to locate sources of exposure to asbestos. Can J Public Health 88:163–8.

Tessari R, Canova C, Simonato L. (2004). Epidemiological investigation on the health status of employees in two factories manufacturing and repairing railway rolling stock: a historical perspective study of mortality. Med Lav 95:381–91.

Thermal Insulation Manufacturers Association (TIMA) Nomenclature Committee. 1993. Man-made vitreous fibers: nomenclature, chemical and physical properties. Washington, DC: Refractory Ceramic Fibers Coalition (RCFC). 72 p.

Travis LB, Curtis RE, Glimelius B, et al. (1995). Bladder and kidney cancer following cyclophosphamide therapy for non-Hodgkin's lymphoma. J Natl Cancer Inst 87:524–30.

Trethowan WN, Burge PS, Rossiter CE, et al. (1995). Study of the respiratory health of employees in seven European plants that manufacture ceramic fibers. Occup Environ Med 52:97–104.

Tsai RJ, Luckhaupt SE, Schumacher P, et al. (2014). Acute myeloid leukemia risk by industry and occupation. Leuk Lymphoma 55:2584–91.

Twight C. (1991). From claiming credit to avoiding blame: the evolution of congressional strategy for asbestos management. J Public Policy 153:155–6.

U.S. Environmental Protection Agency (U.S. EPA). (2009). Toxicological review of tetrachloroethylene (perchloroethylene) (CAS No. 127-18-4), in Support of Summary Information on the Integrated Risk Information System. Report EPA/635/R-08/011A. Washington, DC: U.S. EPA. 537 p.

U.S. Environmental Protection Agency (U.S. EPA). (2012). Toxicological Review of Tetrachloroethylene (Perchloroethylene) (CAS No. 127-18-4) in Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-08/011F U.S. Washington DC: EPA. 1077 p.

Utell MJ, Maxim LD. (2010). Refractory ceramic fiber (RCF) toxicity and epidemiology: a review. Inhal Toxicol 22:500–21.

Vucenik I, Stains JP. (2012). Obesity and cancer risk: evidence, mechanisms, and recommendations. Ann N Y Acad Sci 1271:37–43.

Walker AM, Maxim LD, Utell M. (2012a). Are airborne refractory ceramic fibers similar to asbestos in their carcinogenicity? Inhal Toxicol 24:416–24.

Walker AM, Maxim LD, Utell M. (2012b). Corigendum. Are airborne refractory ceramic fibers similar to asbestos in their carcinogenicity? Inhal Toxicol 24:928–9.

Wang BJ, Lee JY, Wang RC. (1993). Fiberglass dermatitis: report of two cases. J Formos Med Assoc 92:755–8.

Wang P, Liu H, Jiang T, Yang J. (2015). Cigarette smoking and the risk of adult myeloid disease: a meta-analysis. PLoS One 10:e0137300.

Weikert S, Ljungberg B. (2010). Contemporary epidemiology of renal cell carcinoma: perspectives of primary prevention. World J Urol 28:247–52.

Welch LS. (2007). Asbestos exposure causes mesothelioma, but not this asbestos exposure: an amicus brief to the Michigan Supreme Court. Int J Occup Environ Health 13:318–27.

Wild P, Gonzalez M, Bourgkard E, et al. (2012). Occupational risk factors have to be considered in the definition of high-risk lung cancer populations. Br J Cancer 106:1346–52.

Winer A, Holtgren WD. (1976). Asbestos – a case study of the U. S. Navy's response to upgraded safety and health requirements. Safety Division Naval Sea Systems Command. Naval Eng J 88:41–8.

Wong O. (2001). Malignant mesothelioma and asbestos exposure among auto mechanics: appraisal of scientific evidence. Regul Toxicol Pharmacol 34:170–7.

Wong O. (2006). The interpretation of occupational epidemiologic data in regulation and litigation: studies of auto mechanics and petroleum workers. Regul Toxicol Pharmacol 44:191–7.

Wu X, Lin J, Grossman HB, et al. (2007). Projecting individualized probabilities of developing bladder cancer in white individuals. J Clin Oncol 25:4975–81.

Zeeb H, Blettner M. (1998). Adult leukaemia: what is the role of currently known risk factors? Radiat Environ Biophys 36:217–28.

Zeegers MP, Swaen GM, Kant I, et al. (2001). Occupational risk factors for male bladder cancer: results from a population based case- cohort study in the Netherlands. Occup Environ Med 58:590–6.

Zeegers MP, Tan F, Dorant E, Van Den Brandt P. (2000). The impact of characteristics of cigarette smoking on urinary tract cancer risk: a meta-analysis of epidemiologic studies. Cancer 89:630–9.

Zhang L, Steinmaus C, Eastmond DA, et al. (2009). Formaldehyde exposure and leukemia: a new meta-analysis and potential mechanisms. Mutat Res Rev Mutat Res 681:150–68.

Zhu X, Li T, Wang H. (2015a). Relationship between dust mass concentration and fiber number concentration of refractory ceramic fibers. Chin J Ind Hyg Occup Dis 33:309–12.

Zhu X, Li T, Wang H. (2015b). Effects of refractory ceramic fibers on workers' pulmonary ventilation function. J Environ Occup Med (Chinese) 32:399–403.

Zhu X, Li T, Wang H. (2015c). Effects of refractory ceramic fibers on workers' skin. J Environ Occup Med (Chinese) 5:404–8.

Zhu X, Li T, Wang H. (2015d). Analysis of occupational exposure levels to fibrous dust for refractory ceramic fiber workers. Chin J Ind Med 2:98–101.

## Appendix

Table A1. Known risk factors for kidney cancer.

| Site | Risk factor | Comments | Sources |
|---|---|---|---|
| Kidney cancer | Cigarette smoking | Strong evidence from cohort, case–control and meta-analysis studies in several countries indicates tobacco (particularly cigarette) smoking is a major risk factor. | Brown et al., 2012; Chow & Devesa, 2008; Hunt et al., 2005; Janout & Janoutová, 2004; Karami et al., 2012; Lipworth et al., 2009; Ljungberg et al., 2011; McLaughlin et al., 2006; Moyad 2001; Orth, 1997; Pascual & Borque, 2008; Qayyum et al., 2012; Rubagotti et al., 2006; Weikert & Ljungberg 2010; Zeegers et al., 2000. |
| | Obesity | Strong evidence from several studies that elevated body mass index (BMI) is a risk factor for kidney cancer. | Anderson et al., 2015; Brown et al., 2012; Chow et al., 2000, 2010; Chow & Devesa, 2008; Janout & Janoutová, 2004; Karami et al., 2012; Lipworth et al., 2009; Ljungberg et al., 2011; Mariusdottir et al., 2016; McLaughlin et al., 2006; Moyad, 2001; Qayyum et al., 2012; Rubagotti et al., 2006; Song et al., 2014; Vucenik & Stains, 2012; Weikert & Ljungberg 2010. |
| | Drugs | Mixed evidence relating to certain analgesics and diuretics. | Chow et al., 2010; Ljungberg et al., 2011; Rubagotti et al., 2006. |
| | Medical conditions and treatments | Hypertension is known risk factor for kidney cancer. Certain other diseases implicated (e.g. end stage, chronic kidney disease and long term dialysis). There are others including genetic factors and a family history of kidney cancer. There is a possible link to history of diabetes mellitus. | Chow et al., 2000, 2010; Chow & Devesa, 2008; Janout & Janoutová, 2004; Karami et al., 2012; Lipworth et al., 2009; Ljungberg et al., 2011; Mariusdottir et al., 2016; McLaughlin et al., 2006; Moyad 2001; Pascual & Borque, 2008; Qayyum et al., 2012; Rubagotti et al., 2006; Russo, 2012; Weikert & Ljungberg 2010. |
| | Occupational | "Renal cell cancer generally is not considered an occupational disease" (Chow et al., 2010), but occupational exposure to several chemicals (e.g. benzene, benzidine, coal tar, soot, pitch, gasoline, trichloroethylene, tetrachloroethylene, various metals (lead, cadmium), poly-aromatic hydrocarbons and solvents) implicated as risk factors. Employment in several sectors (e.g. agriculture, coke and coal oven workers, computer manufacturing, drycleaners, painters, mechanics, roofers, shipbuilders and textile workers), but evidence is mixed. | Chiu et al., 2013; Chow et al., 2010; Heck et al., 2010; Hu et al., 2002; Karami et al., 2011; Kim et al., 2014; Ljungberg et al., 2011; Mariusdottir et al., 2016; Moore et al., 2010; Partanen et al., 1991; Pascual & Borque, 2008; Pesch et al., 2000; Rubagotti et al., 2006; USEPA, 2009, 2012. |

Table A2. Known risk factors for bladder cancer.

| Site | Risk factor | Comments | Sources |
|---|---|---|---|
| Bladder cancer | Cigarette smoking | Tobacco smoking is the best established risk factor for bladder cancer. Numerous review articles, epidemiological studies (e.g. cohort and case–control) and meta-analyzes indicate that there are statistically significantly elevated odds ratios and high population attributable risks associated with smoking. | Baris et al., 2009; Brown et al., 2012; Brownson et al., 1987; Burger et al., 2013; Cassidy et al., 2009; Freedman et al., 2011; Ghadimi et al., 2015; Golka et al., 2007; Hemelt et al., 2009; IARC, 2004; Olfert et al., 2006; Orth, 1997; Silverman et al., 2006; Zeegers et al., 2000 |
| | Obesity | Strong evidence from meta-analyzes that obesity is also a major risk factor for bladder as well as kidney cancer. | Koebnick et al., 2008; Qin et al., 2013; Song et al., 2014; Sun et al., 2015 |
| | Medical conditions and treatments | Chronic bladder infections and irritations, personal or family history of bladder cancer, Some medications and dietary supplements – pioglitazone (Actos), aristolochic acid (mainly from plants in the Aristolochia family) and cyclophosphamide therapy. Schistosomiasis. | Burger et al., 2013, Lewis et al., 2011; Mostafa et al., 1999; Travis et al., 1995; http://www.medicalnewstoday.com/articles/167077.php. |
| | Occupational | Cohort and case–control studies have shown that occupational exposure to several chemicals (e.g. arsenic, paint components, dry cleaning fluids, polycyclic aromatic hydrocarbons, aromatic amines, diesel exhausts, lubricating oils or greases, petroleum product or additives, tetrachloroethylene and aromatic amines) linked to bladder cancer – strength of evidence varies. Employment is certain sectors (e.g. agricultural workers, bartenders, blacksmiths, bus drivers, dyers, painters, hairdressers, leather workers, maintenance workers, mechanics, medical workers, metal workers, miners, rubber industry, textile workers, transportation equipment, truck and bus drivers and waiters) also linked to bladder cancer, but strength of the evidence varies. | Brown et al., 2012; Brownson et al., 1987; Burger et al., 2013; Cassidy et al., 2009; Clapp et al., 2008; Ghadimi et al., 2015; Golka et al., 2004, 2007; González et al., 1989; Harling et al., 2010; Khoubi et al., 2013; Kogevinas et al., 2003; Lynge et al., 2006; McLaughlin et al., 2006; Olfert et al., 2006; Reulen et al., 2008; Richardson et al., 2007; Scarselli et al., 2011; Serra et al., 2008; USEPA, 2012; Wu et al., 2007; Zeegers et al., 2001. |

Table A3. Studies on irritant contact dermatitis and fiber exposure.

| Type of article | Typical results/statement | Source(s) |
|---|---|---|
| Review articles | Summarize other research findings that indicate fibers with diameters greater than those of respirable size are more likely to cause skin irritation. | ATSDR (2004)<br>Björnberg (1985)<br>INSERM (1999) http://www.ipubli.inserm.fr/bitstream/handle/10608/192/?sequence =10.<br>Lachapelle (1986, 2006)<br>Possick et al. (1970)<br>Sertoli et al. (1992)<br>Skotnicki-Grant (2008) |
| Focus groups | Interviews with workers exposed to insulation materials that contain some mention of the role of larger diameter fibers. | Lundgren et al. (2014) |
| Patch or rubbing test results | Patches containing fibers applied to skin of test subjects indicating larger diameters are associated with greater skin response. | Eun et al. (1991)<br>Stam-Westerveld et al. (1994) |
| Miscellaneous other studies | Coarse fibers account for irritation | Heisel & Hunt (1968)<br>Minamoto et al. (2002)<br>Patiwael et al. (2005) |
| Case reports | One or several cases of contact irritant dermatitis caused by fibers with diameters greater than those of respirable size. | Chang et al. (1996)<br>Koh et al. (1992)<br>Lee & Lam (1992)<br>Sim & Echt (1996)<br>Wang et al. (1993) |
| Epidemiological studies | Studies of groups of occupationally exposed workers showing large diameter fibers associated with skin irritation. | Hsieh et al. (2001)<br>Kieć-Świerczyńska & Wojtczak (2000) |
| Medical texts | Glass fibers with diameters greater than ~5 μm are more likely to cause skin irritation than smaller diameter fibers | Adams (1990)<br>Rom & Markowitz (2004)<br>Kanerva et al. (2013)<br>Konzen (1987) |

Table A4. Causes, contributing factors and risk factors for adult leukemia.

| Category | Examples | References |
|---|---|---|
| Occupational | Exposure to benzene and certain other chemicals (e.g. ethylene oxide (b), formaldehyde (a), pesticides, herbicides, insecticides, embalming chemicals, toluene and xylene). | Adegoke et al., 2003: Brown et al., 1990; Costantini et al., 2008; Deschler & Lübbert, 2006; Glass et al., 2003; IARC, 2012; Rinsky, 1989; Rodriguez-Abreu et al., 2007; Schwilk et al., 2010; Smith & Zhang, 1998; Zeeb & Blettner, 1998; Zhang et al., 2009 |
| | Electromagnetic fields | Floderus et al., 1993; Karakosta et al., 2016; Rodriguez-Abreu et al., 2007 |
| | Radiation | Band et al., 1996; Deschler & Lübbert, 2006; Greaves, 1997; Karakosta et al., 2016; Leuraud et al., 2015; Richardson et al., 2015; Rodriguez-Abreu et al., 2007; Smith & Zhang, 1998; Zeeb & Blettner, 1998 |
| Lifestyle-related | Smoking | Brownson et al., 1993; Danaei et al., 2005; Fernberg et al., 2007; Fircanis et al., 2014; Kane et al., 1999; Karakosta et al., 2016; Smith & Zhang, 1998; Wang et al., 2015 |
| | Obesity | Calle et al., 2003; Castillo et al., 2012; Larsson & Wolk, 2008; Strom et al., 2009 |
| | Diet | McDonald et al., 2001; Ross et al., 2002; Smith & Zhang, 1998 |
| Environmental | Radon exposures in the home. | Henshaw et al., 1990 |
| Medical procedures | Chemotherapy (certain drugs) and therapeutic radiation. | Aidan et al., 2013; Curtis et al., 1992; Deschler & Lübbert, 2006; Zeeb & Blettner, 1998 |
| Genetic disorders | Down syndrome, Klinefelter syndrome, Patau syndrome, Ataxia telangiectasia, Shwachman syndrome, Kostman syndrome, Neurofibromatosis, Fanconi anemia and Li-Fraumeni syndrome. | Deschler & Lübbert, 2006; Zeeb & Blettner, 1998 |
| Certain viral infections | Infection with the human T-cell lymphoma/leukemia virus-1 (HTLV-1) can cause a rare type of T-cell acute lymphocytic leukemia. Most cases occur in Japan and the Caribbean area. In Africa, the Epstein-Barr virus (EBV) has been linked to Burkitt lymphoma, as well as to a form of acute lymphocytic leukemia. In the US, EBV most often causes infectious mononucleosis ("mono"). | Matsuoka & Jeang, 2007; De Roos et al., 2013; Rodriguez-Abreu et al., 2007 |
| Family history | Family history of leukemia or any cancer. | Karakosta et al., 2016; Rauscher et al., 2002 |

(a) Some reported associations are controversial, such as the relation between occupational exposure to formaldehyde and leukemia (Collins & Lineker, 2004; Heck and Casanova, 2004).
(b) IARC (2012) concluded that there is limited human evidence for the carcinogenicity of ethylene oxide.

# APPENDIX B:

## Audit Report

## Quality Assurance Audit of Personal Exposure Monitoring for Refractory Ceramic Fibers at the Morgan Thermal Ceramics, Augusta, GA Facility February 1, 2022

### Introduction and Background

In 2017, the High Temperature Insulation Wool Coalition (HTIWC) and its member companies published the fourth iteration (since 2002) of their worker protection program entitled Product Stewardship Program (PSP) 2017. As part of this program personal and area exposure monitoring for refractory ceramic fibers is conducted at HTIWC facilities (internal) and customer facilities (external). Monitoring is conducted by the industrial hygiene staffs of the HTIWC member companies.

The earlier published Quality Assurance Project Plan (PSP QAPjP) outlines procedures for sample collection and analysis. The QAPjP calls for periodic sampling audits which are quality assurance checks of individuals collecting airborne fiber samples. This includes a review and observation of the sampling procedures (as outlined in the QAPjP) during collection of samples designated for inclusion in PSP 2017. Sampling audits are performed by independent industrial hygiene consultants retained by the HTIWC.

This report summarizes an internal sampling audit conducted by Eva M. Ewing, CIH of W.M. Ewing & Company at the Morgan Thermal Ceramics facility in Augusta, Georgia. Personal exposure monitoring was performed by [redacted], Environmental Health and Safety/Industrial Hygiene Technician, of Thermal Ceramics. [redacted] EHS Manager, was also on-hand to discuss PSP activities. Ms. Ewing accompanied [redacted] throughout the day on February 1, 2022 when he conducted personal exposure monitoring for RCF fibers at the facility.

The Morgan Thermal Ceramics facility produces RCF fiber and makes various RCF materials at the Augusta, Georgia site. The day of the sampling audit, [redacted] monitored five workers doing the following job categories: 1) auxiliary – one electrician working in the shop and various locations in the pant and one person retrieving samples from the plant and working in the lab, and 2) assembly – two workers encapsulating Superwool with a foil-like wrap and ) fiber production – one worker chopping Cerofiber.

Prior to conducting the sampling audit Ms. Ewing reviewed the procedures in the QAPjP. The Sampling Audit Checklist included in Appendix D of the PSP 2012 QAPjP was used as a tool for conducting the audit and is attached to this report. Each of the audit items are discussed below.

### Customer Contact Form Completed

The customer contact form is not required for internal sampling.

### Walk-Through of Facility

[redacted] has been at the facility for a few years and is familiar with the operations that were monitored. He provided Ms. Ewing with a tour of the portions of the plant where he was conducting monitoring and demonstrated knowledge of the processes and job functions.

**Review Work Process, Procedures & Previous IH Monitoring Data**

[redacted] and [redacted] discussed the previous sampling data for the facility with Ms. Ewing.

**Document Engineering Controls and Work Practices**

[redacted] documented engineering controls and/or conditions on the industrial hygiene data sheets. [redacted] also documented protective respiratory equipment worn by the employee chopping fiber.

**Develop Sampling Strategy**

[redacted] used the random selection list for the first quarter of 2022 that was provided by the consultant to select the workers that were monitored (attached).

**Assign Functional Job Category to Employees Monitored**

Functional job categories were appropriately assigned to employees monitored in accordance with the QAPjP. The functional categories assigned to the workers encapsulating the Superwool with the foil-like wrap were all in the Assembly category. The Electrician and the Laboratory employee were in the Auxiliary category and the employee chopping fiber was in the Fiber Production category

**Select Employees to be Monitored**

Selection of employees for monitoring was done in accordance with the QAPjP as described above.

**Appropriate Sampling Equipment on Hand**

The sampling equipment used was consistent with the requirements of NIOSH 7400 and included new Casella personal air sampling pumps calibrated at a nominal flow rate of 1.25 liters/minute; Tygon tubing; and 25-millimeter (mm) diameter, mixed cellulose ester (MCE) membrane filter cassettes with 50 mm extension cowls. A Gilian bubble meter was used to calibrate the pumps.

**Sampling Pumps Charged Prior to Use**

The pumps were charged prior to use and ran without interruption for the entire shift.

**Equipment Maintenance Log Available and Current**

All of the pumps that were new and had not yet been serviced this year. [redacted] and [redacted] indicated an equipment maintenance log will be prepared for the pumps when needed. The Gilian primary flow calibrator had been serviced and calibration was current.

**Sampling Pumps Calibrated Prior to Use**

Sampling pumps were calibrated prior to use by [redacted] with a Gilian primary flow calibrator (electronic bubble meter).

**Conduct Sampling of Employees: Record Start/Stop Times, Cassette Numbers, Job Tasks, Controls, Collect Field Blanks**

Start and stop times and cassette numbers were recorded on the industrial hygiene data sheets along with the employee's name, job title and job tasks (functional activity category). One field blank was collected. Sampling was conducted in accordance with good industrial hygiene practice by placing the sampling cassette in the breathing zone of the worker's (lapel). Pumps and tubing were checked frequently to assure they were functioning properly.

**Inspect Cassette Filters During Sampling. If Necessary, Change The Cassette (To Prevent Overloading)**

[redacted] inspected the cassettes several times for each worker and changed them about every 2 hours during the shift to prevent overloading.

**Change Filter Cassette if Employee Crosses Functional Job Categories**

The functional job categories for the workers did not change throughout the shift.

**Calibrate Sampling Pumps After Sampling Is Complete**

[redacted] properly calibrated the pumps at the end of the sampling period. Post calibrations were within 5% of pre-calibrations.

**Complete Industrial Hygiene Data Sheet**

Review of the industrial hygiene sampling sheets indicated they had been correctly completed for each employee monitored.

**Complete Analysis Request Form (usually done at office)**

[redacted] demonstrated the proper method of completing the analysis request forms while the auditor was on-site.

**Samples Packaged for Shipment (usually done at office)**

[redacted] explained the method that would be used to package the samples for shipment. He indicated that he typically uses newspaper if packing material is necessary.

**Summary of Observations**

Procedures outlined in the QAPjP were utilized by [redacted] to collect personal samples during this audit. The sampling was conducted in accordance with NIOSH Method 7400, with good industrial hygiene practice, and in a careful manner. [redacted] demonstrated knowledge of procedures outlined in the QAPjP. He observed and questioned employees about their activities and the products used throughout the shift and recorded it on the data sheets. [redacted] clearly had good rapport with the workers. Based on the observations made during this audit, the sampling procedures used will provide reliable, representative data for the activities monitored and there are no recommendations for changes to the procedures.

**Report prepared by:**

Eva M. Ewing, CIH, FAIHA
Senior Industrial Hygienist
W.M. Ewing & Company

02/4/22
Date

# PSP 2002 Field Audit Checklist

| Audit Item | Satisfactory | Unsatisfactory | Comments |
|---|---|---|---|
| Customer Contact **Form** Completed | | | Not Applicable |
| Walk-through of facility (if necessary) | | | Not Necessary |
| Review work process, procedures, & previous IH monitoring data (if available) | X | | |
| Document engineering controls & work practices | X | | |
| Develop sampling strategy | X | | Conducted in Accordance with 1st Quarter Internal Selection List |
| Assign functional job category to employees monitored | X | | |
| Select employees to be monitored | X | | |
| Appropriate sampling equipment on hand | X | | |
| Sampling pumps charged prior to use | X | | Calibration for Gilian Gilibrator was current |
| Equipment **maintenance log** available & current | X | | Log for new sampling pumps will be developed when they are serviced |
| Sampling pumps calibrated prior to use (Pre-calibration) | X | | |
| Conduct sampling of employees: record start/stop times, cassette numbers, job tasks, controls, collect field blanks | X | | |
| Inspect cassette filters during sampling. If necessary, change the cassette (to prevent overloading) | X | | Cassettes changed out approximately every 2 hours |
| Change filter cassette if employee crosses functional job categories | | | Not Applicable |
| Calibrate sampling pumps after sampling is complete | X | | |
| Complete Industrial Hygiene Data **Sheet** | X | | |
| Complete Analysis Request **Form** (usually done at office) | X | | |
| Samples packaged for shipment (usually done at office) | X | | Packaging process explained |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Eva M. Ewing
Auditor Name (Print)

Eva M Ewing
Auditor Signature

2/1/22
Date of Audit

Person Conducting Monitoring: [redacted], ESH/IH Technician with Thermal Ceramics

# Thermal Ceramics
# 29th Year Internal Selection, First Quarter 2022

## Augusta

| FJC | Selected Job Name | Number Selected | Total Samples |
|---|---|---|---|
| Assembly | Encapsulation | 2 | 2 |
| Modules | Module making & misc. fabrication | 1 | 1 |
| Auxiliary Operations | END CONES QUALITY CONTROL | 1 | 5 |
| | R&D & QA Technician | 1 | |
| | Mechanic, Standard & Converted Fiber | 1 | |
| | Electrician, standard & converted fiber | 1 | |
| | ~~Shipping, Forklift Driving~~ | 1 | |
| Fiber Production | Blowing Bagger/Chopper | 1 | 10 |
| | ~~BLOWING HELPER (NON BAGGER)~~ | ~~2~~ | |
| | ~~BLOWING LINE/ FURNACE OPERTAOR~~ | 1 | |
| | ~~Needler Repair~~ | 1 | |
| | SHOT DRYER | 1 | |
| | ~~SPUN CLEANUP~~ | 1 | |
| | ~~SPUN LINE OPERATOR~~ | 1 | |
| | ~~Spun Truck Driver~~ | 1 | |
| | ~~S.KAOWOOL TRACTOR DRIVER~~ | 1 | |
| ~~Finishing~~ | ~~Board Finishing~~ | 1 | 4 |
| | ~~END CONES PACKER M 1 2 & 3~~ | ~~3~~ | |
| Mixing/Forming | ~~ABM Batching Forming~~ | ~~2~~ | 5 |
| | [redacted]ine Washed Fiber Line | 1 | |
| | TBM Batching Forming | 1 | |
| | ~~End Cones Operator & Batch Man (Machine 1,2, & 3)~~ | 1 | |
| ~~Other (NEC)~~ | ~~Paper Line Operator~~ | 1 | 3 |
| | ~~Offline Slitter~~ | 1 | |
| | ~~End Of Paper Line~~ | 1 | |

Total = 30

# APPENDIX C

## Sample Data Collection Sheet

**INDUSTRIAL HYGIENE SAMPLE DATA SHEET**

| SAMPLE ID: | COMPANY (COMPANY) | FIB/SIL (FIB/SIL) | METHOD (METHOD) | DATE (DATE) | IH (IH) | CUSTOMER (CUSTOMER) | 1 (WORKER) |
|---|---|---|---|---|---|---|---|

| | | | |
|---|---|---|---|
| FACILITY NAME | ☐ Special Emphasis Sample | EMPLOYEE NAME | |
| LOCATION | | DEPT/POS'N | |
| DATE | DATE | FUNCT. CATEGORY | SOURCE (P,V,O) |
| CONTACT INFO | NAME<br>PHONE # | # SHIFTS | SHIFT (1,2,3,O) |
| RESPIRATOR (TYPE) | | HTIW MATERIALS USED (check fiber type(s) and describe)<br>☐ RCF ☐ AES ☐ PCW ☐ Other | |
| OTHER PERSONAL EQUIPMENT | | | |

| IND. SEG. | PUMP CALIBRATION | | | | |
|---|---|---|---|---|---|
| PUMP # | TIME | PRE CAL | TIME | POST CAL | AVG |
| | : | | : | | |
| PUMP # | TIME | PRE CAL | TIME | POST CAL | AVG |
| | : | | : | | |

FUNCT. CATEGORIES:

| | |
|---|---|
| 1 = FIBER | 6 = M/F |
| 2 = FIN | 7 = AUX |
| 3 = INST | 8 = OTH |
| 4 = REM | 9 = MODULES |
| 5 = ASBLY | |

NUMBER OF WORKERS IN EACH FJC AT THIS FACILITY (CUSTOMERS ONLY--LEAVE BLANK FOR MFG SAMPLES)

| ASBLY | AUX | FIN | INST | M/F | OTHER | REM | TOTAL |
|---|---|---|---|---|---|---|---|
| | | | | | | | 0 |

MATER'LS MADE / APPLICATION

OBSERVATIONS ON ADMIN. AND ENG. CONTROLS:

GENERAL COMMENTS / TRAINING TYPE

# TRAINED

| CAS. ID NUMBER | PUMP NUMBER | START TIME | STOP TIME | MINUTES | VOLUME | RESULTS (f/cc) | TLA | JOB/ TASK | COMMENTS/ OBSERVATIONS | SUBTRACT MINUTES | () () |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |
| | | : | : | | | | | | | | |

| | | | |
|---|---|---|---|
| 0 (TOT. TIME) | 0 (TOT. VOL) | (ACT. TWA) | CALIBRATION BY: (SIGNATURE) |
| | | (8 HR TWA) | DATA COLLECTED BY: (SIGNATURE) |

INDUSTRY SEGMENTS: P = PRODUCER
VF = VACUUM FORMER F = FABRICATION
FR = FURNACE RELATED R = RESALE
O = OTHER (NEC)