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Workplace Monitoring of Occupational Exposure to Refractory Ceramic Fiber—A 17-Year Retrospective

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This article presents a 17-year (1990–2006) retrospective summary of ongoing studies of occupational exposure to refractory ceramic fiber (RCF) in the United States. Beginning in 1990, RCF producers integrated and harmonized individual workplace monitoring programs to provide data useful for various longitudinal and cross-sectional analyses, benchmarking, and various technical analyses. For 10 of these 17 years, the program has been conducted in partnership with government agencies, first a 5-year (1993–1998) program with the U.S. Environmental Protection Agency and later another 5-year (2002–2006) program with the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health. This article updates earlier published studies and provides lessons to be learned in the design of industrial hygiene monitoring and control programs.

This article provides an update to ongoing monitoring studies of occupational exposure to refractory ceramic fiber (RCF) at plants that produce RCF and customer facilities in the United States. It is relevant to those with a particular interest in RCF and, more generally, to readers interested in product stewardship programs (PSPs), the design of exposure monitoring programs, and the analyses of data from these programs.

BACKGROUND

RCF (Chemical Abstract Service [CAS] no. 142844-00-6) is an amorphous synthetic vitreous fiber (SVF). Other SVFs include glass wool fibers, rock (stone) wool fibers, slag wool fibers, and special-purpose glass fibers. RCF is a high-temperature insulating refractory used chiefly in industrial applications. The history, chemical and physical properties, production methods, occupational exposure, and commercial applications are

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summarized in several studies (see, e.g., Mast et al., 2000a, 2000b; Maxim et al., 1994, 1997, 2000a, 2000b). In brief:

- RCF was first produced on an experimental basis in the early 1940s and commercialized during the 1950s in the United States, in 1968 in Europe, and in 1975–1976 in South America and Australia. Today RCF is produced in many countries and used in most industrialized countries. In Europe, for example, RCF is produced in the Czech Republic, France, Germany, Poland, and the United Kingdom. Major European consumers of RCF include Belgium, France, Germany, Italy, Spain, the Netherlands, and the United Kingdom (ERM, 1995). RCF is a niche product, accounting for 1–2% of the total worldwide SVF production.
- RCF is produced by melting and spinning or blowing a mixture of alumina and silica and/or calcined kaolin. Other inorganic oxides, such as zirconia and boria, are sometimes added to alter the properties of the resulting product.
- Useful physical/chemical properties of RCF include a high maximum end use temperature (up to 1430°C, depending upon composition), low thermal conductivity, low bulk density, low volumetric heat capacity (heat storage), flexibility and moldability, resistance to thermal shock and chemical corrosion, good acoustical and fire protection properties, and ease of installation (see, e.g., ERM, 1995). These properties make it suitable as energy-efficient high-temperature insulation for furnaces, heaters, and reactors used in many industrial sectors, including the aerospace, automotive, cement, ceramic, chemical, forging, foundry, glass, nonferrous metals, petroleum, and petrochemical industries. RCF saves energy in high-temperature applications and, among other things, reduces emissions of greenhouse gases and the environmental impacts of energy production (ECA, 1996; Wimmer & Class, 2002; Wimmer, 2005).
- In contrast to most SVFs, RCF is principally an industrial product; exposure is limited to an industrial cohort. In the United States, it is estimated that the exposed cohort includes approximately 30,000 workers (ECA, 1992; Maxim et al., 2000a). In Europe in 1995 it was estimated that the exposed cohort was approximately the same (ERM, 1995).

As produced and/or handled, some RCF is respirable (for length–diameter distributions of RCF in occupational exposures see, e.g., Mast et al., 2000a; Maxim et al., 2000a). Additionally, RCF is relatively durable and biopersistent compared to many (but not all) SVFs, although very much less biopersistent than amphibole asbestos (see data from various sources summarized in Brown et al., 2005; Maxim et al., 2006). Because of its respirability and durability, RCF might pose an occupational health hazard. The desire to identify, control, and reduce any risk of occupational illness from the manufacture, processing, or use of RCF led manufacturers to develop a comprehensive and unified PSP (see Barrows et al., 1993), shown schematically in Figure 1.

FIG. 1. Key elements of the product stewardship program for RCF.

This article focuses on two components of this PSP, exposure monitoring and the development of workplace controls over the 17-year period from 1990 to 2006.

MONITORING PROGRAM HISTORY IN BRIEF

This section provides a brief history of the monitoring program. Table 1 provides a summary of key dates.

Prior to 1990 each of the domestic RCF producers operated independent exposure monitoring programs at their plants in the United States, Canada, and Puerto Rico (see Esmen et al., 1979; TIMA, 1990; Corn et al., 1992). These were limited, for the most part, to internal monitoring of exposures, although some customers were also monitored (Maxim et al., 1994, 1997, 2000a). Data were analyzed by the same National Institute for Occupational Safety and Health (NIOSH) 7400A (post-1990 by 7400B) techniques, but earlier data were collected by the various producers using slightly different protocols, analyzed by different laboratories, and were based (in part) on purposive, rather than random, sampling. These (and later data) were analyzed to assess historical exposures to support ongoing epidemiological studies carried out by the University of Cincinnati (see, e.g., Hall et al., 1997; Rice et al., 1994, 1997, 2005).

Several changes to the exposure monitoring component of the PSP were made in 1990 to bring these monitoring programs into closer alignment, to increase the number of data fields,[1] and to implement random sampling in order to provide representative samples of worker exposure. (Some purposive sampling, chiefly to learn more about specific exposures and to evaluate engineering controls, continued, but these data were segregated from the main database.) Exposure data were shared among RCF manufacturers. Data collected using random sampling are termed historical baseline samples. To facilitate use of a common

TABLE 1
Brief chronology of relevant milestones in high-temperature wools exposure monitoring program

Year	Event
1985	RCF industry establishes recommended exposure guideline (REG) of 2 fibers (f)/ml on the basis of prudence and demonstrated feasibility
1987	Epidemiology study started with University of Cincinnati; work begins on reconstruction of historical exposures
1990	Separate exposure monitoring programs in each firm integrated into common program; random sampling introduced and customer sampling budgets increased
1991	REG lowered from 2 f/ml to 1 f/ml on basis of prudence and demonstrated feasibility
1992	Exposed cohort size estimated at approximately 30,000 workers
	Industry completes feasibility study with OSHA and concludes that 1 f/ml is technically and economically feasible. OSHA proposes permissible exposure limit (PEL) of 1 f/ml, but this standard (among many others) vacated by courts
1993	Five-year Consent Agreement signed with U.S. EPA; formal quality assurance project plan employed and additional data captured
1996	Monitoring program expanded to Europe designed to control and reduce exposure (CARE); European exposed cohort estimated to be same size as U.S. cohort.
	Firms in RCF industry commercialize, alkaline earth silicate (AES) wools, a less biopersistent substitute for RCF in selected applications
1997	REG lowered from 1 f/ml to 0.5 f/ml on basis of prudence and demonstrated feasibility
1998	Consent Agreement expires, but industry continues monitoring program
1999	AES wools included in exposure monitoring program
2002	PSP 2002, a voluntary 5-year monitoring program, developed with OSHA; additional features (included expanded outreach and training programs) and enhancements added; NIOSH becomes partner in new program
2004	NIOSH work on efficient controls for disk sanding published summarizing development of improved controls for this application
2006	NIOSH publishes Criteria Document for RCF summarizing available information on health effects and exposure; NIOSH establishes REL of 0.5 f/ml with action level of 0.25 f/ml for RCF; PSP 2002 program completed
2007	New 5-year monitoring program, termed PSP-HTW, initiated with OSHA oversight, NIOSH continues as partner

collection and analysis protocol and to maintain the confidentiality of certain proprietary data (such as customer identities), the monitoring data were maintained and analyzed by an independent firm (Everest Consulting Associates).

In 1993, the Refractory Ceramic Fibers Coalition (RCFC, an RCF industry group focused on stewardship) industry signed a 5-year Consent Agreement with the U.S. Environmental Protection Agency (EPA) to continue monitoring efforts. The U.S. EPA concluded as part of its assessment of possible RCF risks that additional data on occupational exposure were needed. Input from the RCFC and other interested parties (e.g., labor and user groups) was solicited and the participants developed workplace and worker sampling schemes, protocols for the collection and analysis of fibers, and provisions for the evaluation of the resulting data.

The U.S. EPA commented favorably on the PSP in the official announcement of the monitoring program Consent Agreement (58 *Federal Register* No. 92, May 14, 1993, p. 28517).[2] The Consent Agreement employed a comprehensive quality assurance project plan (QAPjP) with explicit data quality objectives (DQOs), followed good laboratory practice (GLP), employed the same laboratory to analyze all samples, and included periodic audits of the collection and analysis procedures. Additional ancillary data were included among the many enhancements made to the program in 1993.

The sampling program systematically included customers (first-tier customers[3]) and was based on a stratified random sampling plan (SRSP). The sampling strata included workers in eight specific functional job categories (FJCs)—broad occupational categories that were expected to have different average exposures-and sampling budgets (the number of samples collected in each FJC for plants operated by RCF producers and at customer facilities) were selected to optimize the statistical efficiency of the plan.[4] Between 1990 and 1998 the domestic RCF industry collected over 6200 samples.[5] (A sample, as used herein, includes as many cassettes [typically 1–4] as needed to properly calculate a time-weighted average [TWA] fiber concentration.[6]) Worker monitoring continued using essentially the same collection and analysis protocols after the expiration of the Consent Agreement in 1998.

In 1996 the RCF industry expanded the statistically based monitoring program to include plants in Europe as part of an ongoing initiative to Control and Reduce Exposure, known by its acronym CARE. The analysis of CARE data has been described (Maxim et al., 1998a). (In Europe, as in the United States, exposure data were collected prior to the use of a SRSP.) In Europe, as in the United States, epidemiological studies of workers were carried out. Exposure monitoring was one component of these studies (Cherrie et al., 1989; Groat et al., 1999; Miller et al., 2007).

One of the achievements of the PSP was the development of a new class of high-temperature insulating wools, termed alkaline earth silicate (AES) wools, capable of replacing RCF in many (but not all) applications (see, e.g., Maxim et al., 1999a). AES wools have lower biopersistence, one of the determinants of fiber toxicity. In 1999 the scope of the monitoring program was broadened to include measurements of TWA concentrations of these new materials.

In 2002, RCFC and its member companies initiated a 5-year voluntary product stewardship program, called PSP 2002, to continue these monitoring efforts (among other things) working cooperatively with the Occupational Safety and Health Administration (OSHA); NIOSH and the U.S. EPA also participated. The PSP 2002 monitoring program was similar to the earlier program with the U.S. EPA, but incorporated various enhancements and modifications based on lessons learned. PSP 2002 monitoring was completed in December 2006. PSP 2002 was judged successful by both the RCF industry and its government partners[7] and in May 2007 both parties agreed to yet another 5-year program, called PSP-HTW,[8] to continue the monitoring program through at least 2011.

Between 1 January 1990 and the same date in 2007, the domestic industry (excluding Europe and data collected by individual customer facilities) collected over 10,000 historical baseline samples. Together with data from Europe (another 5700 TWA samples), these data are the most comprehensive compilation of occupational RCF exposure information available. The present monitoring program in the United States collects a minimum number of 250 historical baseline samples annually at RCF manufacturing facilities and an identical number of samples from customer facilities. Historical baseline samples are personal monitoring samples analyzed by phase-contrast optical microscopy (PCOM). Additional samples, termed special emphasis samples (SES), are also collected for special studies, such as the development of improved engineering controls. SES include both personal monitoring and area samples. (SES collection totals are not included in the data counts already given here.)

Though not formally part of the RCF producer monitoring program(s), several RCF converters and users (customers) established independent monitoring programs. These vary in breadth and depth. Some customers (see later discussion) have elected to share data with RCF producers, and these data are maintained in a separate database.[9]

The vast majority of RCF occupational exposure data have been collected as part of the industry PSP. However, many other investigators (see, e.g., Cheng et al., 1992; Friar & Phillips, 1989; Gantner, 1986; Head & Wagg, 1980; Hori et al., 1993; Kauffer & Vincent, 2007; Krantz et al., 1994; Perrault et al., 1992; Rogers et al., 1997; van den Bergen et al., 1994; Verma et al., 2004; Wojtczak, 1994; Wojtczak et al., 1996, 1997) have also published RCF exposure data. Where possible, the industry attempts to make comparisons with other exposure measurements as an overall consistency check, but these data are not pooled with the historical baseline samples because other investigators typically did not collect exposure data using the same protocol and sampling plans as those reported herein and/or reported only data summaries. Yet other studies have measured fiber concentrations for less than a full-shift average. Unless the actual job duration is less than a full shift (as it is for some removal operations), such measurements represent task length averages (TLAs)[10] and cannot be compared directly with 8-h TWAs.[11] Even if pooling were feasible and appropriate, the incremental precision resulting from use of pooled data would not be great given the large size of the industry database.

OBJECTIVES AND USES OF MONITORING DATA—AND SOME LESSONS LEARNED

The RCF exposure monitoring program has several objectives, including, for example:

- Evaluation of the success of the PSP in meeting various occupational exposure limits (OELs); in the United States this means compliance with the industry's current recommended exposure guideline (REG) of 0.5 fibers per milliliter (f/ml).
- Estimation of time trends in weighted average workplace fiber concentrations (longitudinal analysis) to track the progress of the industry in reducing RCF exposures at both RCF manufacturing and customer facilities.
- Studies of differences (cross-sectional analyses) in workplace concentration among workers in various FJCs, identifying high-exposure jobs (and, within these, high-exposure tasks).
- Studies of firm-to-firm, plant-to-plant, or manufacturer–customer differences for common FJCs. These analyses (when properly interpreted) can be used for benchmarking purposes and identifying "best practices."
- Assessment of the effectiveness of specific control measures and technologies, for example, the use and type of local exhaust ventilation (LEV), hand versus mechanical tools for finishing operations, "waterlance" removal of after-service insulation, and other processes or operations.
- Measurement of workers' use of personal protective equipment (PPE), such as respirators to reduce effective exposure (Maxim et al., 1998b).

- Measurement of overall exposures at RCF manufacturing and customer facilities. When coupled with dosimetry and potency information, these exposure data are potentially useful for risk analyses.
- Measurement of cumulative exposure of various worker cohorts (and subgroups) in support of ongoing epidemiological studies.

Various other technical analyses are possible using these data (see, e.g., Maxim et al., 1997, 1998a, 1998b, 1999b, 2000a, 2000b). Identification of the objectives of monitoring is an important first step in developing an efficient sampling plan (experimental design) and the particular data (including ancillary data) to be collected. As noted in the historical summary given earlier, the sampling plan (and specific data collected) has evolved over the years based on lessons learned and shifts in the relative priority of the monitoring objectives.

One general lesson learned is that it is important to think carefully about the ancillary data to be collected. For example:

- Data are collected on whether or not a respirator is properly worn by each worker when sampled and, if so, the make and model of respirator used. This enables (among other things) estimates to be made of each worker's effective exposure allowing for the protective effect of respirators and other analyses described below. The need and utility of this type of analysis was not anticipated prior to 1993 and the program was modified to collect these data at that time. As it was not possible to collect these data retroactively, all such analyses involving respirator use are limited to the post-1993 period.
- The sampling strata are based on FJCs. However, FJCs (even at the individual plant level) are too broad to be regarded as homogeneous exposure groups (HEGs). For this reason, ancillary data are collected on the specific tasks and work stations where various tasks are performed. (The epidemiology study uses "dust zones" [selected using methods described in Corn and Esman, 1979] as the basic identification of workstations.) Thus, it is possible to disaggregate the strata into various subpopulations to learn more about the determinants of exposure.
- Over the years, progressively more information has been collected on the specific fiber (there are various RCFs [differing in composition and whether spun or blown] and, more recently AES wools manufactured by the industry) used by the worker as well as the form (e.g., blanket, bulk, board, paper, felt) used in each task performed by the worker. These data can be used to learn if there are material differences in concentration among fiber types or forms.

Subject to feasibility constraints, experience suggests that it is probably better to collect too much ancillary information than too little. If these candidate determinants of exposure are later shown to be unimportant, they can subsequently be dropped from the program.

Another lesson learned is the utility of having explicit DQOs, such as the desired precision of various exposure estimates, to be used in deriving sample budgets in the SRSP. Fiber concentration data are highly variable (e.g., even at the plant FJC level the coefficient of variation or ratio of the standard deviation to the mean, σ/μ, is often $\geq$1) and this fact is a key determinant of the number of samples required.

The design of the program and types of analysis to be performed has benefitted greatly from the suggestions (and occasional requirements) of regulatory agencies. Over the years OSHA, the U.S. EPA, and NIOSH have made valuable suggestions to improve the program. For example, one useful collaboration with NIOSH personnel led to the development of more efficient control techniques during disk sanding (Dunn et al., 2004). One of the basic goals of the PSP is to maintain a cooperative relationship with regulatory and advisory agencies. Among the many benefits of this partnership are the ideas and insights of government officials—this is a fundamental lesson for others seeking to develop a similar program.

DISCUSSION OF RESULTS

This section presents updated and/or more comprehensive information on the results of the monitoring program. It is organized in terms of the key monitoring objectives.

Compliance With REG

As noted earlier, the present REG for RCF is 0.5 f/ml, a number identical to the recommended exposure limit (REL) established by NIOSH in its 2006 Criteria Document (NIOSH, 2006). The REG was established on the basis of feasibility and prudence, not demonstrated risk; over the years the REG (and individual company forerunners) has been reduced, most recently from 1.0 f/ml to 0.5 f/ml in 1997. Data for the most recent monitoring year (2006) indicate that (on a weighted average basis, weights determined by the fraction of the workers in each FJC) 95.8% of workers at RCF manufacturing plants were exposed to TWA concentrations $\leq$0.5 f/ml (uncorrected for the protective effects of respirator use) and 97.9% had exposures beneath the REG when adjusted for respirator use. Among customers the corresponding percentages were 83.4% and 90.1%. (These percentages are based on measured concentrations on the day sampled, not on long-term averages.) Thus, compliance with the REG in 2006 was quite high and has been so for many years.

NIOSH also recommended an action level (AL) for RCF (NIOSH, 2006); following established practice the AL was set at one-half the REL or 0.25 f/ml in this case. Maintaining exposures beneath the action level provides a reasonable statistical guarantee that (allowing for variability in exposures and exposure measurements) that long-term average exposures are beneath the REG or REL. The AL can also serve as a useful "trigger" for additional monitoring and exposure reduction efforts. Based on weighted average data for 2006, approximately 80% of workers at RCF manufacturing plants and 66% of workers at customer facilities were exposed to TWA concentrations less than or equal to the action level.

Distribution of Workers Among FJCs

Although workers may engage in jobs from more than one FJC, workers are assigned to FJCs (i.e., the population is stratified) on the basis of the typical jobs performed. It is necessary to estimate the numbers of workers in each stratum in order to develop an efficient stratified sampling plan and also to correctly weight the respective stratum means to calculate weighted average exposures. Changing market conditions (e.g., demand shifts) and productivity increases mean that the distribution of workers among FJCs changes with time. Figure 2 shows the most recent distribution of workers among FJCs for workers in RCF manufacturing plants and at customer locations. As can be seen, these distributions are quite different. Only workers in RCF manufacturing facilities engage in fiber production, for example, and only customers engage in installation and removal activities. Thus, there are jobs that are unique to each group. Additionally, there are differences in the percentage of workers among the common FJCs. For these and other reasons, it is necessary to collect data on the distribution of workers among FJC.

Time Trends in RCF Exposure

Figure 3 shows weighted average TWA concentrations (annual averages) for workers in RCF manufacturing plants (denoted by filled circles) and at customer facilities (denoted by filled squares) over the period from 1990 to 2006. The solid

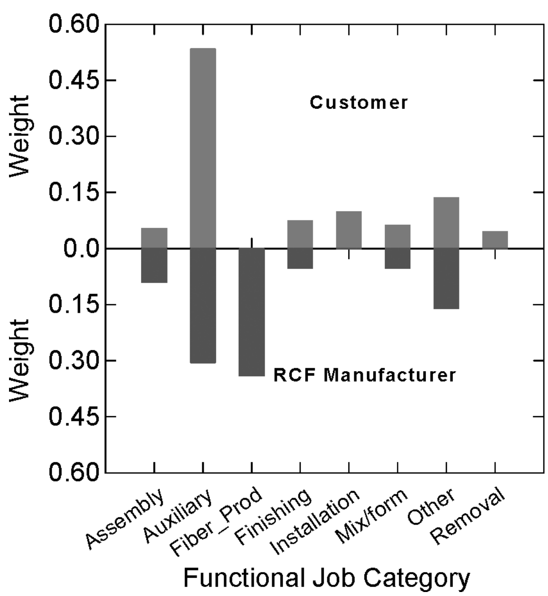

FIG. 2. Distribution of workers among FJCs for customers and RCF manufacturers in 2006.

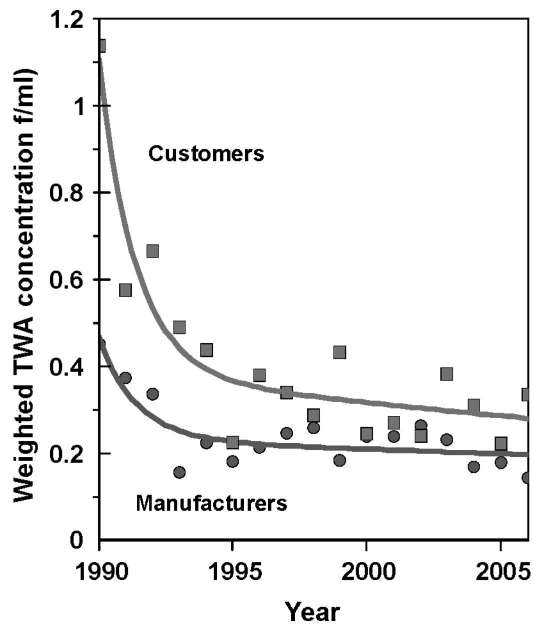

FIG. 3. Weighted average TWA concentrations from 1990–2006 for workers in RCF manufacturing plants and at customer facilities.

lines shown in Figure 3 are trend lines fitted by nonlinear least squares. These exposures are as measured and not adjusted for the protective effects of respirators.

Three features of these data are noteworthy:

- Weighted average TWA fiber concentrations have decreased substantially for both groups over this time period—there is evidence that the PSP has been successful in reducing exposures.
- Exposures at customer facilities have been greater than corresponding average for workers at RCF manufacturing plants, but the difference (gap) between these two groups has narrowed over the years. This provides evidence that manufacturer outreach efforts have been successful and that control technology transfer has occurred.
- The rate of improvement in fiber concentration has slowed in recent years as fiber concentrations have become lower. This result is plausible and consistent with earlier indications (Maxim et al, 1994, 1997, 2000a). Control efforts are directed at those opportunities that offer the greatest incremental benefits; as the program becomes more mature, the attractive opportunities are gradually exhausted and progress slows.

RCF manufacturers remain committed to a goal of continuous improvement. Time will tell whether or not the practical limits of control have been reached or whether further reductions are feasible. The specific model used to generate the curves in Figure 3 is $Y_t = \beta_0 \exp(-\beta_1 t) + \beta_2 \exp(-\beta_3 t)$, where Y_t is the weighted average TWA concentration (for either RCF producers or customers) in year t, and β_0, β_1, β_2, and $\beta 3$ are empirical constants fitted by nonlinear least squares. Other models (e.g., learning curve models, exponentials with or without asymptotes) have similar values for R^2, but different predictions for the long term, so whether or not further exposure reductions are feasible cannot be determined directly from these data.

Improvements by FJC

Figure 3 shows weighted average TWA concentrations. As noted above, the universe of jobs has been partitioned into eight FJCs (sampling strata). These include assembly, auxiliary, fiber production, finishing, installation, mixing/forming (to produce vacuum formed shapes), other (not elsewhere classified), and removal of after-service insulation. The weights (shown in Figure 2) are determined from the percentages of workers in each FJC for manufacturers and customers. Earlier studies (Maxim et al., 1994, 1997, 2000a) have shown that exposures vary significantly among these FJCs—one of the reasons that an efficient SRSP can be developed.

Figure 4 shows average TWA concentrations by FJC at RCF manufacturing plants comparing two 5-year periods, one at the beginning of the harmonized exposure monitoring period (1990–1994) and the other for the most recent five year period (2002–2006). Only six FJCs are plotted in this figure because (as noted earlier) RCF producers do not engage in furnace installation or removal of after-service RCF. For either of the two time periods, there are statistically significant differences in TWA fiber concentrations among the FJCs. Exposure differences between the two 5-year periods are significantly different for assembly, fiber production, finishing, and mixing/forming. The degrees of exposure reduction differ among FJCs, reflecting differences in emphasis and opportunity:

- Finishing, for example, has been a particular target for improvement, even though only a relatively small percentage of the RCF manufacturing workforce are engaged in this activity (5% in 2006) because exposures in finishing have been higher on average than those in other categories. Finishing entails such operations as sanding and sawing; the mechanical energy used for this activity creates dust and elevated fiber concentrations. Methods for exposure reduction in finishing include the use of down draft tables and tools fitted with dust capture equipment.
- Fiber production has also been a target for improvement because a large percentage of the manufacturing workforce (34% in 2006) is engaged in this FJC. The data in Figure 4 show that fiber concentrations in this FJC have been reduced materially.
- Improvements in the auxiliary FJC have been small and not statistically significant because (among manufacturers) these exposures were low to begin with.

Figure 5 shows the same information as that presented in Figure 4 for workers at customer facilities. Statistically significant reductions in TWA fiber concentrations have been achieved for finishing, installation, and the auxiliary category. Again the pattern of differences in the degree of exposure reduction reflects differences in both emphasis and opportunity. There has been no reduction in the measured average TWA for removal of after-service insulation. Removal operations take place at remote job sites where is has proven difficult to use traditional engineering dust controls to advantage. Instead, workers in this

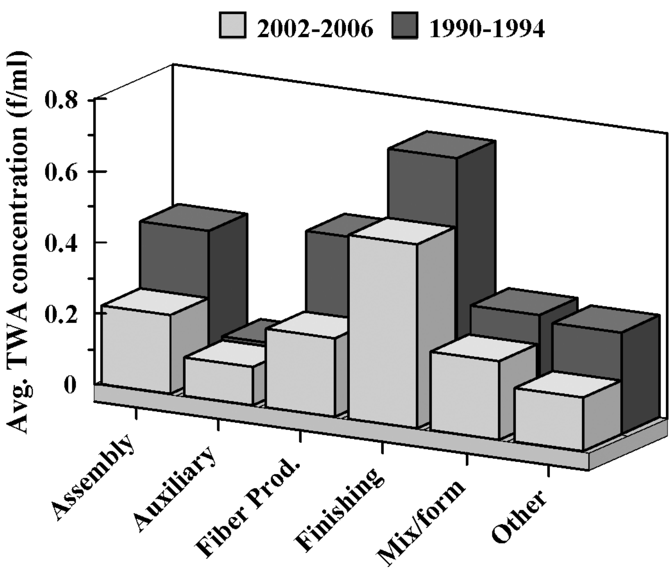

FIG. 4. Average TWA fiber concentrations by FJC of RCF manufacturing facilities, 1990–1994 compared to 2002–2006.

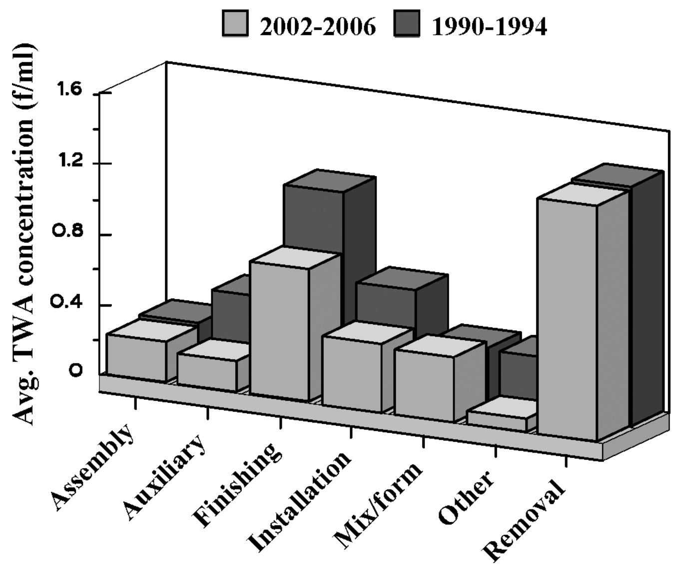

FIG. 5. Average TWA fiber concentrations by FJC of customer facilities, 1990–1994 compared to 2002–2006.

FJC (approximately 4% of the total) use respirators to control exposure. Effective exposures corrected for respirator use are presented later.

Differences Between Manufacturers and Customers

As noted earlier, the gap between the average exposure of workers in RCF production plants and those in customer facilities has been narrowing, an indicator of PSP success. This gap exists for two reasons: (1) Workers in RCF production plants perform different jobs than those in customer facilities, and (2) exposures differ between manufacturers and customers for the same job categories. Workers at customer facilities (at least some of them) perform installation and removal of after-service insulation; those in RCF production plants do not perform either of these jobs. As can be seen from Figure 5, installation and removal are relatively high-exposure jobs (absent any allowance for the protective effect of respirators). And workers in customer facilities do not produce fiber, as is done in manufacturing plants. Unique jobs account for part of the observed gap between manufacturers and customers.

However, it is also true that workers in customer facilities (still) have higher average exposures than workers in RCF manufacturing facilities for common FJCs. Figure 6 shows these differences by FJC for the most recent 5-year period (2002–2006). Differences are statistically significant for the auxiliary, finishing, mixing/forming, and other (customers lower in this FJC) categories. These differences have narrowed over time, but have not yet been eliminated.

Differences Among Jobs/Tasks Within FJCs

Though useful for developing an efficient SRSP, the partition of all jobs into eight FJCs is relatively coarse. That is, work-

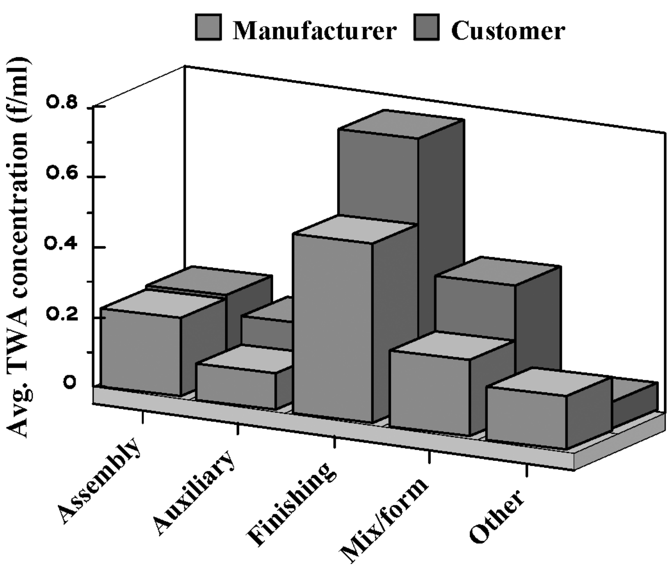

FIG. 6. Manufacturer and customer exposures compared for common FJCs. Dates are for the period 2002–2005.

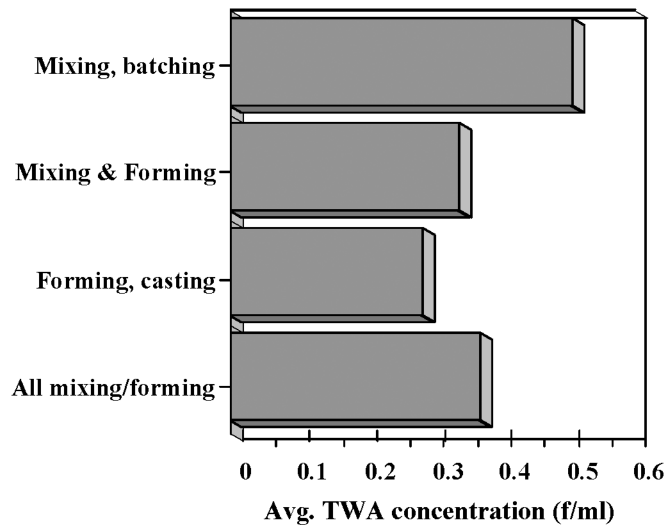

FIG. 7. Differences among jobs in the mixing/forming FJC among customers (2002–2006).

ers in the same FJC (either at manufacturing plants or customer facilities) engage in a variety of different tasks or jobs. Earlier results (see Maxim et al., 2000a) showed that there were statistically significant differences in exposure within an FJC. Analyses of more recent data confirm this finding. Figure 7, for example, shows statistically significant TWA concentration differences among jobs in the mixing/forming FJC. Vacuum forming consists of several sequential steps: (1) mixing RCF and other materials (e.g., binders and fillers) into a water slurry, (2) transferring the slurry to a forming tank where a wire mesh mold is immersed, a vacuum is drawn pulling water through the holes while solids accumulate on the face, and the vacuum is reversed and the wet formed shape is (3) placed in an oven to complete the drying process, and (4) performing finishing activities on the dried pieces/shapes. Mixing and forming are pooled into one FJC. However, as can be seen from the data in Figure 7, exposure differ among those exclusively engaged in mixing, performing both mixing and forming (as is typically done at smaller facilities), and those exclusively engaged in forming (also termed casting). The rank order of the exposure results is as expected because the mixing operation entails placing dry bulk RCF in the mixing tank, an activity that results in higher exposures.

Mixing/forming is one of several FJCs where there are statistically significant within FJC differences; finishing in another (Maxim et al., 2000a). And there are several significant differences between plants within an FJC (see discussion on benchmarking later).

Effective Exposures Accounting for the Effects of Respirator Use

It is recognized that there is a hierarchy of exposure control methods: engineering controls, workplace practices, and use of

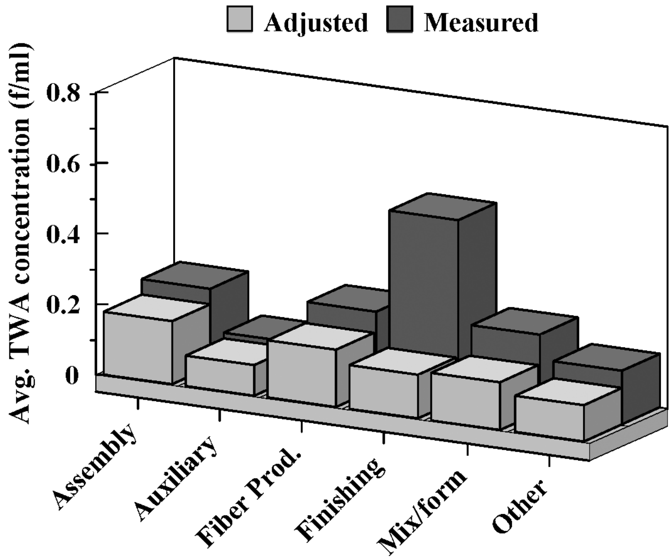

FIG. 8. Measured and effective RCF TWA concentrations by FJC for manufacturers (2002–2006).

PPE. Nonetheless, there are certain jobs for which engineering controls and modified workplace practices are not sufficient to reduce exposures to target levels and respirators must be used. As noted earlier, ancillary data collected as part of the monitoring program includes (for each worker monitored) whether or not a respirator is worn and, if so, the make and model of the respirator (thus the assigned protection factor [APF]). Thus, it is possible to estimate the effective exposure allowing for the protective effect of respirators (Maxim et al., 1998b, 2000a).

Figure 8 shows measured and effective (i.e., corrected by the APF for workers wearing respirators) RCF TWA concentrations for workers in RCF manufacturing plants by FJC over the most recent 5-year period from 2002 to 2006. Three features of these data are noteworthy:

- Effective exposures are substantially beneath measured exposures for certain categories. In the finishing FJC, for example, the average measured exposure is 0.52 f/ml, whereas (allowing for the protective effect of respirators for those workers wearing respirators) the effective exposure is 0.13 f/ml.[12] As noted, for example, it is relatively difficult to control exposures in the finishing FJC.
- Effective exposures differ little from measured exposures in relatively low-exposure jobs (e.g., auxiliary) because exposures are low to begin with and respirators are not needed, and therefore, not used extensively in these categories.
- Although there is statistically significant variability in measured TWA concentrations among FJCs, much of this variability is eliminated through use of respirators for high-exposure jobs. The range between the highest and lowest measured average TWA concentrations is 0.41 f/ml; when adjusted for respirator use, this range is lowered to 0.05 f/ml. Indeed, the rank ordering of FJCs differs when comparing measured and effective exposures. Jobs with relative low exposures remain low when corrected for respirator use because respirators are typically not used. Jobs with relatively high measured exposures have relatively low effective exposures because respirators are used more frequently.

At manufacturers and customers alike, workers are typically free to wear respirators for any job, but required to wear respirators for certain high-exposure jobs. There is persuasive evidence (see Maxim et al., 1998b) that the probability that a worker wears a respirator increases with the TWA fiber concentration. The relationship between these two quantities is termed a respirator response function (RRF). In particular, Maxim et al. (1998b) showed that a simple model could account for the observed behavior. This model assumed that a certain fraction, γ, of workers elect to wear a respirator regardless of estimated fiber concentration. The remaining fraction, $(1-\gamma)$, elect (or are required) to wear a respirator with probability depending upon the estimated fiber concentration, f. A simple exponential model $[1 - \exp(-\theta f)]$ was found to provide an adequate representation of the probability function among "probabilistic users" (those whose usage depends upon fiber concentration). Thus, the fraction, p, of workers who wear a respirator when exposed to a fiber concentration f is given by the simple expression $p = \gamma + (1-\gamma)[1 - \exp(-\theta f)]$. Figure 9 shows the observed proportion of workers wearing respirators at RCF manufacturing facilities (the bars) and the fitted proportion using the simple model (solid line)

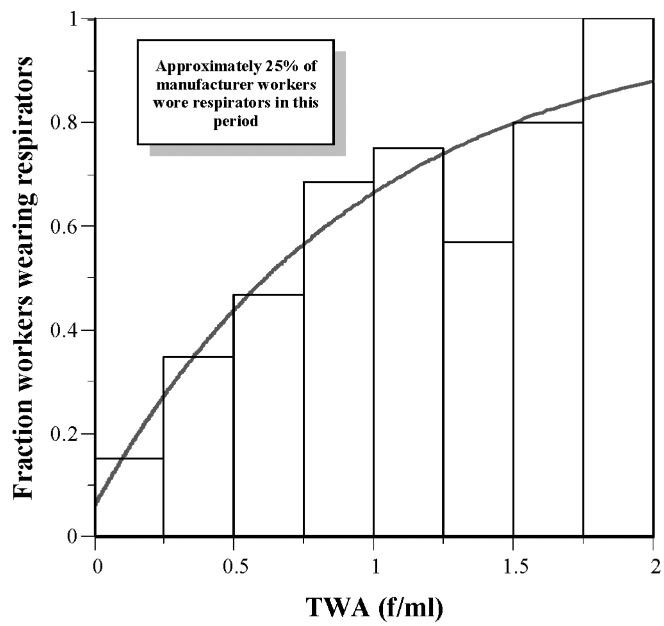

FIG. 9. Observed fraction of workers wearing respirators (bars) and fitted (solid line) using RRF among workers in RCF manufacturing plants (1998-2006).

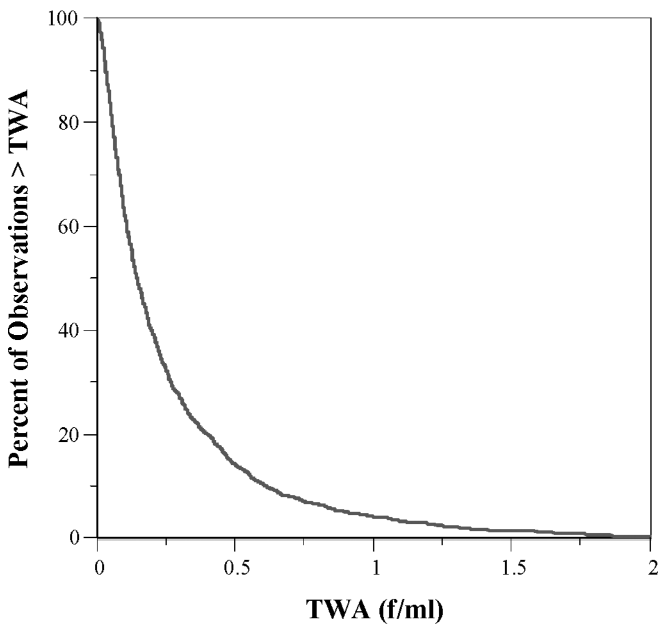

FIG. 10. Distribution of measured exposures at RCF manufacturing plants (1998–2006).

over the period from 1998–2006. In this instance the best fit estimates (using the fitting technique described in Maxim et al., 1998b) of the RRF are $\gamma = 0.06$ and $\theta = 1.03$. As can be seen, the fit is quite good. A possible reason for the increased variability at elevated fiber concentrations is that relatively few jobs had elevated exposures (e.g., above 1 f/ml) and, therefore, the sample size for estimating proportions becomes progressively lower at higher concentrations—a point demonstrated in Figure 10. The standard deviation of an estimated proportion based on n samples is $[p\ (1 - p)/n]0.5$.

Why doesn't respirator use jump more rapidly at higher fiber concentrations? Put differently, why doesn't this curve resemble a step change from zero to one at exactly the REG? At least part of the answer relates to the large variability of fiber concentration measurements. Respirator policies are set based on the expected fiber concentration at a given workstation. But, on any given day, the actual concentration for any job might be higher or lower than the average. This means that on some days a respirator is worn even though the actual concentration is beneath the REG and on other days the concentration is higher than the REG. TWA concentration data are reviewed by the industrial hygienists at RCF manufacturing facilities and changes in respirator policy are made if warranted. At customer facilities, TWA concentration data are provided in a written report to each customer.

The data plotted in Figure 9 span several years. RRFs might be expected to change over time as the REG changes (recall that it was lowered from 1 f/ml to 0.5 f/ml in 1997) and as workers (and management) learn more about the probable exposures for each job and change respirator policies. Figure 11 shows the percentages of workers at RCF manufacturing plants who wear respirators at 3 levels of measured TWA fiber concentrations, <0.5 f/ml, 0.5–1.0 f/ml, and ≥ 1.0 f/ml, as a function of time from 1993 (when respirator use was first monitored and recorded on a systematic basis) until 2006. Although there is year-to-year variability in these percentages, the observed percentages of workers wearing respirators have increased for those workers exposed to higher concentrations and decreased for those exposed to TWA concentrations beneath the REG. The yearly trend of respirator use provides further evidence of program success. This said, the response of the workforce to the lowering of the REL from 1 f/ml to 0.5 f/ml in 1997 was not instantaneous and, on any given day not all workers exposed to more than the REG use respirators at

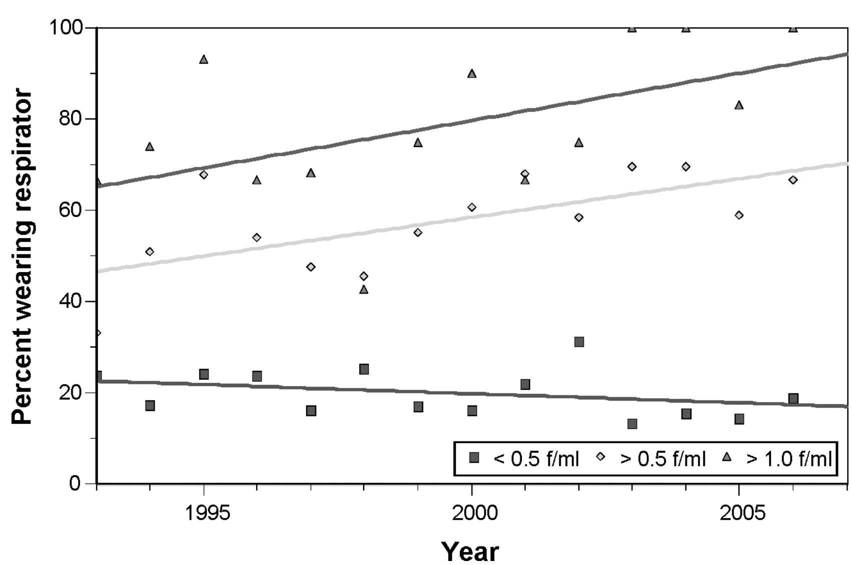

FIG. 11. Observed percentage of workers at RCF manufacturing plants wearing respirators with measured exposures < 0.5 f/ml, ≥ 0.5f/ml, and ≥ 1f/ml from 1993–2006 and fitted trend lines.

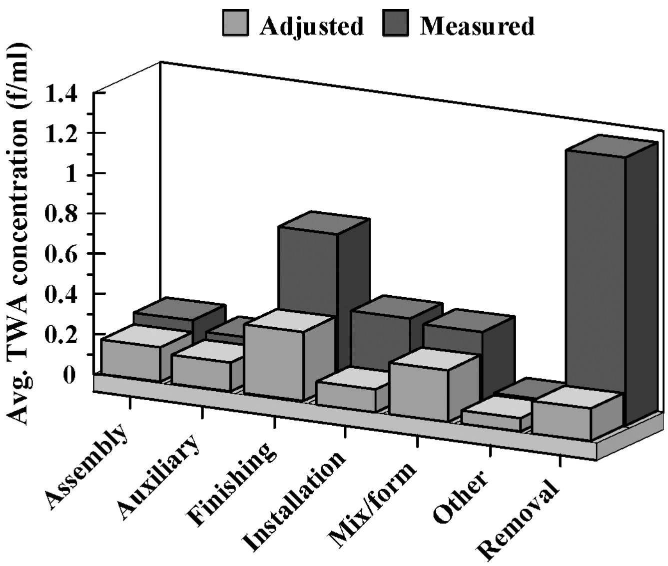

FIG. 12. Measured and effective RCF TWA concentration by FJC for customer facilities (2002–2006).

present—so there is a continuing need to improve. (At present, controls have evolved to the point that only a small proportion of workers are actually exposed to 0.5 f/ml or above, but this does not relieve the industry of the responsibility to protect all workers.)

Figure 12 shows the same information at that presented in Figure 8 except for workers in customer facilities. Similar observations can be made regarding these data:

- Differences between measured and corrected (respirator-adjusted) average concentrations are particularly large for workers engaged in finishing, installation, and removal—categories that have relatively high measured exposures. In removal operations, respirator use is very high because this is the only feasible means of control. (It is not 100% for removal operations because some of these, for example, repair and replacement of a small area of insulation, are typically short and—unlike removal of the complete lining—do not result in high TWA concentrations.) Because the duration of removal operations are typically short, these are difficult to sample—even though sampling is scheduled, it is possible that these are completed ahead of schedule, with the result that the hygienist misses all or part of the removal. Also, because these activities are short, nearly all measurements are actual, rather than 8-h TWAs—thus the exposure dose for removal activities are lower than would be inferred from the TWA.
- Differences are minor for other FJCs, such as auxiliary and other with lower measured exposures.
- As is the case with data from RCF manufactures, use of respirators reduce the overall variability in customer worker exposures. The range between the highest and lowest measured average TWA concentrations is 1.27 f/ml; when adjusted for respirator use, this range is lowered to 0.28 f/ml.

Tracking Changes in TWA Concentrations at the Plant FJC Level

As noted earlier, weighted average TWA fiber concentrations have decreased at both RCF manufacturing plants and at customer facilities. However, it is more difficult to detect significant changes in TWA fiber concentrations at a more disaggregated level. Fiber concentrations are variable for many reasons (see Table 2), and this "noise" makes it difficult to detect the "signal" of changes in average concentration. Rice et al. (2005) and Miller et al. (2007) note that over time RCF fiber concentrations have not changed uniformly (despite overall progress) and some have decreased, increased, or stayed the same at the plant FJC level. Moreover, interpretation of these data is often difficult because of many confounding variables. For example, a decision to relocate a given activity from one plant to another might change the average fiber concentrations at each plant, even though no fundamental process change or incremental controls have been made. A change in the mix of products produced at a given workstation may increase or decrease fiber concentrations even though controls have not improved or otherwise changed. "Designed experiments" are difficult to carry out in full-scale production because of operational limitations.

Figure 13 shows a scatterplot (left) and a box and whisker plot (right) of quarterly measurements of workers engaged in the finishing FJC at one RCF manufacturing plant. Over an extended period of time it is possible to discern a pattern of decreasing exposures. Over the 60-quarter time horizon, numerous changes were made to reduce exposures and evidently these changes were successful; there was a statistically significant decrease in average TWA fiber concentration. Nonetheless, it took many quarters to reliably detect this change and accurately estimate the degree of improvement.

Figure 14 shows a scatterplot (left) and a box and whisker plot (right) of quarterly measurements of workers engaged in the fiber production FJC at another RCF manufacturing plant. Visual inspection suggests that concentrations may actually have increased over this time period, but the confidence interval on the slope of the time trend line includes zero. In any event, fiber production was a category of emphasis in terms of industry exposure reduction efforts and these were apparently unsuccessful for this FJC at this plant.

Figure 15 shows a scatterplot (left) and a box and whisker plot (right) of quarterly measurements of workers engaged in the assembly FJC at an RCF manufacturing plant. There is no apparent (or statistically significant) time trend in these data.

What are the lessons to be learned from these examples? In our view these are:

TABLE 2

Reasons for apparent changes in exposure levels—Why detecting and finding assignable causes for exposure differences are difficult

1.	Change in product mix at workstation or neighboring workstation(s)
2.	Introduction of new products or processes
3.	Modification(s) to existing processes
4.	Productivity gains/losses and resulting shifts in worker composition
5.	Changes in production levels at a workstation or neighboring workstation(s)
6.	Installation of engineering controls (at workstation or neighboring workstation(s))
7.	Change in the location(s) of workstation(s) relative to location(s) of others
8.	Malfunction or gradual deterioration of engineering controls
9.	Refurbishment/repair of controls
10.	Changes in work practices
11.	Worker turnover—worker experience with process
12.	Effects of worker training
13.	Changes in housekeeping and general cleanliness
14.	Change in proportion(s) of time worker spends in various tasks or workstation(s)
15.	Changes in worker height relative to location of LEV pickup points or workstation(s)
16.	Environmental change(s) (e.g., temperature, humidity when sampled, and whether or not windows or doors are open or closed or fans are in use)
17.	Unusual or infrequent activity at workstation or neighboring workstation(s)
18.	Measurement variability
19.	Sampling variability
20.	Unplanned/unrecognized deviations from sampling plan

- No sampling plan is optimal for all objectives. The SRSP to collect historical baseline samples is highly efficient for detection of aggregate trends and for estimation of average exposures by FJC and average exposures for an entire cohort. Aggregate time trends—not merely plant FJC time series—are the appropriate measure of PSP progress. This is a useful lesson to be learned.
- The exposure reduction emphasizes plants and FJCs based on several factors, including (1) the numbers of workers in each FJC, (2) average concentrations in each FJC (with particular emphasis on high-exposure jobs), and (3) assessments of the potential effectiveness of controls for each FJC. This policy means that improvements will be greater in some FJCs than others (consistent with findings of Rice et al., 2005; Miller

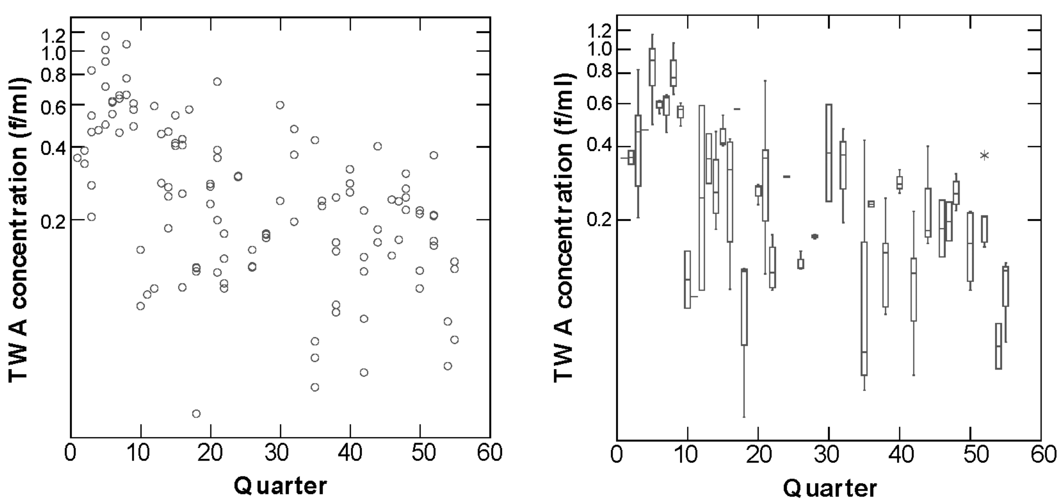

FIG. 13. Scatterplot (left) and box and whisker plot (right) of quarterly measurements of TWA concentrations in the finishing FJC at one RCF manufacturing plant.

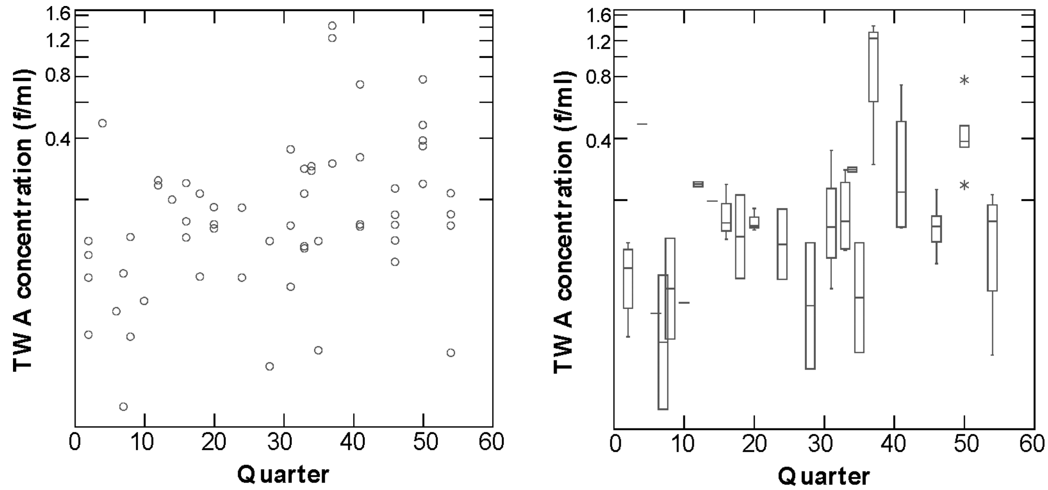

FIG. 14. Scatterplot (left) and box and whisker plot (right) of quarterly measurements of TWA concentrations in the fiber production FJC at another RCF manufacturing plant.

et al., 2007). For example, there has been very little improvement in measured TWA concentrations for removal operations, because engineering controls have not proven successful and respirators remain the best control device.

- Use of historical baseline samples is not efficient for assessing improvement or studying the effectiveness of controls for individual plant FJC workstations. Beginning in 2002 the industry began collecting SES for this purpose. These samples, not part of the historical baseline database, can be used to intensively study individual operations.

Benchmarking

Benchmarking is an integral part of PSP 2002. The intent of benchmarking is to compare the average fiber concentrations in various plants, identify plants with lower exposures, search for assignable causes for these differences, and ultimately share best practices.

For plants operated by RCF producers, average fiber concentrations are compared by FJC on a plant-by-plant basis and the exposure data are shared among RCFC members. This enables RCFC members to identify the plants and processes/operations with relatively high or low fiber concentrations, search for assignable causes, develop lessons learned, and ultimately seek ways to reduce exposure.

Figure 16 presents a bar chart showing the average fiber concentration by FJC by plant for RCF manufacturing plants over the period from 2002 to 2006. It is termed a "skyline" chart because of the resemblance to a city skyline. Referring to Figure 16, it is clear that the average TWA fiber concentration for the finishing FJC at plant A was higher than those for other plants

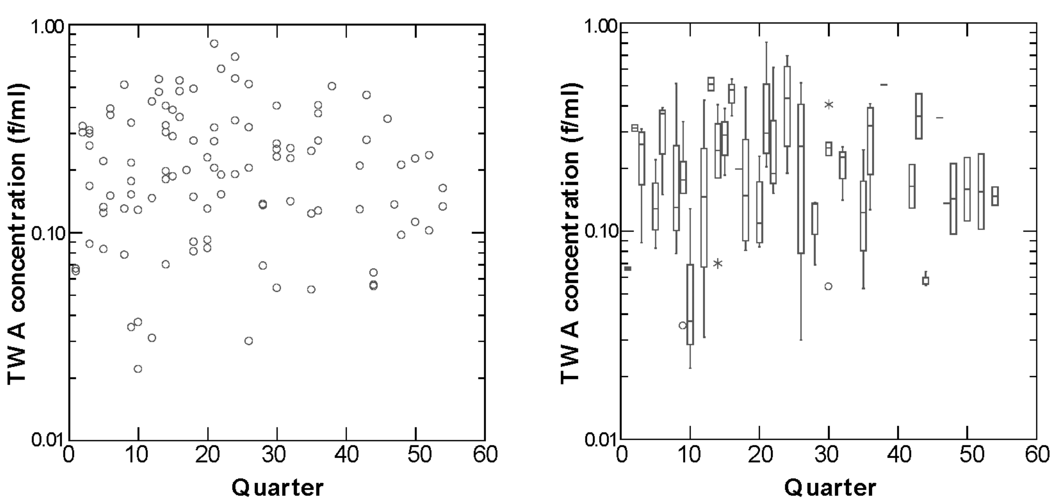

FIG. 15. Scatterplot (left) and box and whisker plot (right) of quarterly measurements of TWA concentrations in the assembly FJC at a RCF manufacturing plant.

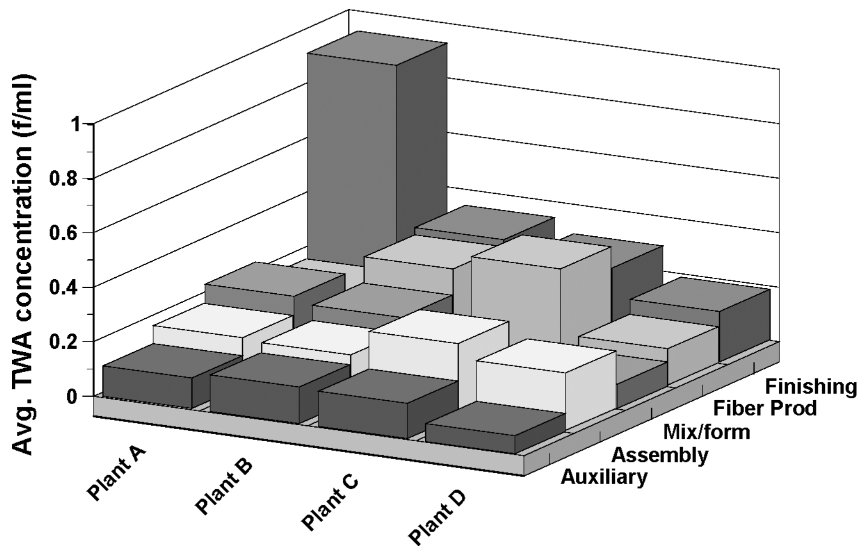

FIG. 16. Average TWA fiber concentration by FJC by plant for RCF manufacturers (2002–2006).

over this period. This was first noted in 2003. The company investigated this situation and has been able to reduce finishing exposures by 43% (2006 compared to 2003) at this facility. (This decrease is not evident in Figure 16 because 5-year averages are plotted.) Finishing operations continue to be studied at this plant and additional engineering controls were installed in 2006; a board sander and saw were modified and additional controls installed.

Care must be exercised in the interpretation of the data shown in Figure 16. It does not follow automatically that all the observed plant-to-plant differences in the fiber concentrations can be eliminated by using improved control practices. There may be material differences in the jobs being performed within the same FJC at different plants. For example:

- RCF produced by different methods (e.g., spinning versus blowing) has different fiber diameters and all fibers as produced have different concentrations of "shot" (unfiberized, nonrespirable material): Other things held constant, typical fiber concentrations are likely to vary with the fiber diameter and (possibly) shot content. Fibers with low shot content have proven to be a good reinforcement material for use in automotive brake linings and other friction materials.
- The mechanical work necessary in the finishing operation varies with the specific product(s) being made and specific finishing steps required.

Differences between measured TWA fiber concentrations should trigger a search for "assignable causes" and the search for improved methods for exposure control. This said, the fact that there are substantial (and statistically significant) differences in TWA concentrations among plants provides hope that further exposure reductions are possible even though the trends shown in Figure 3 appear to offer less encouragement.

For plants operated by (most) customers (see later discussion), exposures are not compared on a plant-by-plant basis because of the large number of facilities. Rather, measured concentration data are aggregated in the form of "ladder diagrams," such as that shown in Figure 17. Using the ladder diagram, data are summarized for a rolling 5-year period (2001 through 2005 in this instance). (The rolling 5-year period is chosen as a practical compromise. On the one hand, it is appropriate to reflect trends, which argues for use of the most recent data. But, on the other hand, because the TWA concentration data are highly variable, it would be appropriate to lengthen the period for comparison so that more data can be included.)

Figure 17 shows the percentage of observations (at customer facilities) at or beneath any specified fiber concentration for each FJC for this time period. Each customer can compare measurement results for their facility (for each FJC) with a statistical profile of comparable data collected at other customer facilities. For example, a measured TWA of 0.5 f/ml for an employee working in the mixing/forming FJC would be exactly in compliance with the REG (one benchmark for comparison). However (see Figure 17), approximately 78% of observations from the mixing/forming FJC at other customer facilities collected over the previous 5-year period were less than 0.5 f/ml. Thus, although the measured value is in compliance with the REG, it is useful to learn that other customers have been able to control exposures to a greater degree.

Miscellaneous Technical Issues

Over the years, the monitoring program has included several studies designed to investigate various technical issues. For example, as noted earlier, fibers are now counted using NIOSH

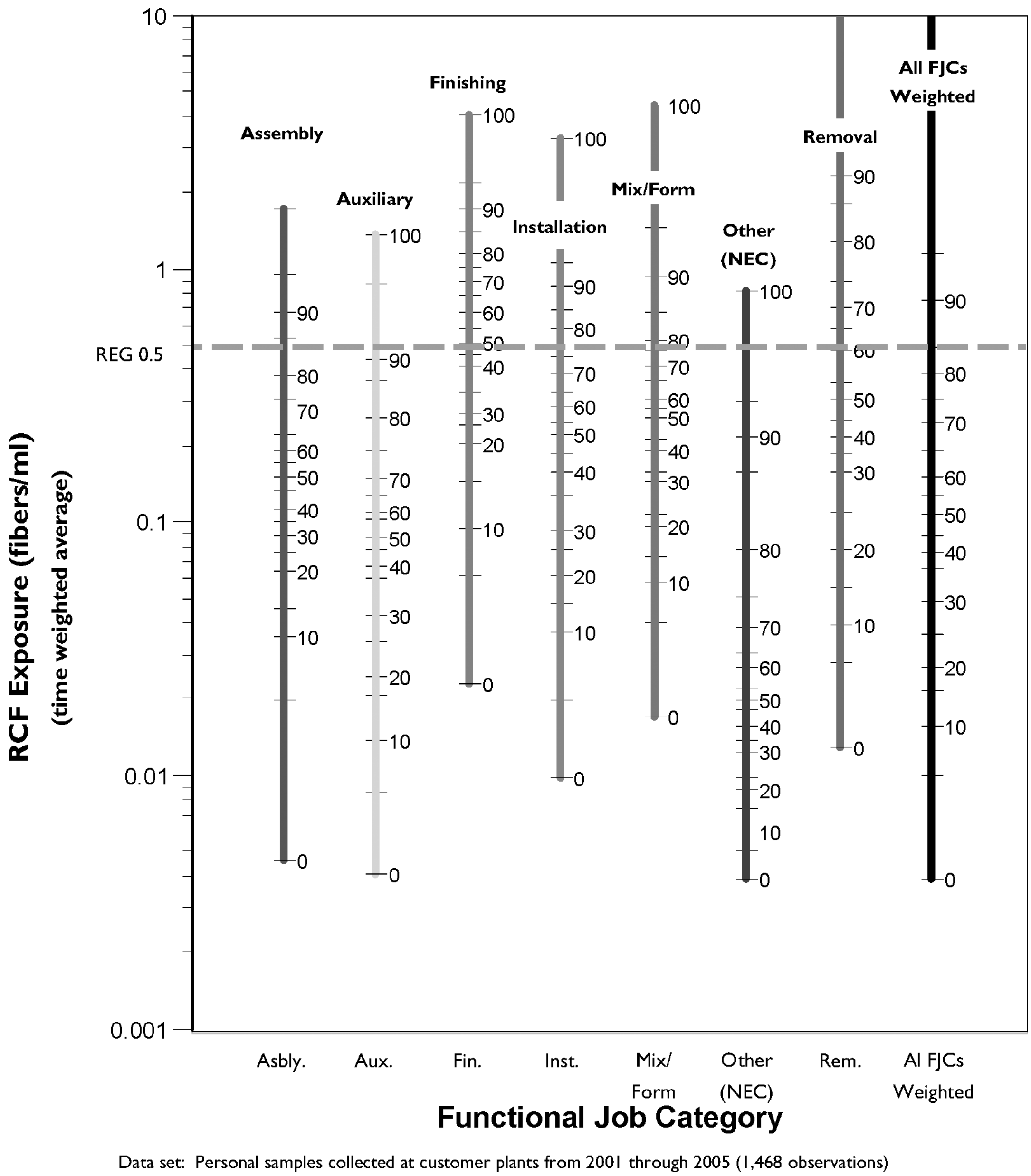

FIG. 17. "Ladder diagram" showing RCF exposures, customers, 2001–2005.

7400B counting rules using PCOM. Because it is of interest to compare fiber concentrations so determined with those based on other counting rules (e.g., World Health Organization [WHO] counting rules) and/or using different measurement methods (e.g., use of transmission electron microscopy [TEM], rather than PCOM) one component of the program used matched samples to be counted and analyzed by different methods. For RCF (see Maxim et al., 1997) specific conversion formulas were derived, but the differences are not large and this component of the program has been terminated.

Another topic investigated as part of this program concerned possible respirable silica concentrations associated with the removal of after-service insulation. RCF is a SVF and does not contain crystalline silica as produced, but can partially devitrify and form quartz, cristobalite, and/or tridymite after being heated. With RCF devitrification is confined to the surface layers (i.e., those near the hot face), but it is still possible that workers who remove after-service insulation might be exposed. Accordingly, the monitoring program collected data on respirable crystalline silica (RCS) exposures of workers engaged in removal. These data were analyzed (see Maxim et al., 1999b) and it was found that most RCS concentration measurements were beneath the limit of detection (LOD); for example, 91% of the respirable quartz concentrations were less than the LOD.

In nearly all cases the LOD was at or beneath the current OSHA permissible exposure limit (assuming 100% silica) of 0.1 mg/m^3. (LODs varied from sample to sample, depending upon the length of the removal task; for respirable crystalline quartz LODs ranged from 0.01 to 0.2 mg/m^3. Most jobs involving removal of after service activities require less than a full shift for completion; among 42 removal operations studied as part of this effort, completion times ranged from 37 to 588 min, with an arithmetic average of 260 min.) Various statistical techniques (Maxim et al., 1999b) were used to estimate mean concentrations in the presence of nondetects. The analysis concluded that most RCS concentrations were beneath the PEL even without any adjustment for respirator use (respirators are typically worn for removal of after-service insulation), but that improved analytical methods with lower detection limits were desirable.

Yet another topic analyzed is the statistical distribution of TWA workplace concentration values. Knowledge of this distribution is important for statistical purposes, such as the analysis of variance and various forms of hypothesis testing. The distribution of concentration levels for many contaminants has been found to be lognormal; the same has been found for fiber concentrations including SVFs, asbestos, and carbon fibers. Figure 18 shows the distribution of fiber concentrations in the assembly FJC for one of the RCF manufacturing plants plotted on log-probability axes. (These are the same data plotted in Figure 15.) A box and whisker plot of TWA concentration is shown at the top of this illustration. If the data followed exactly a lognormal distribution, the plot shown in Figure 18 would be a straight line; as can be seen this is approximately the case for these data. For data from many plant FJC combinations the lognormal plots are almost exactly linear after any time trends are removed.

Because the TWA fiber concentration data are approximately lognormal, it is appropriate to use log transforms of the concentration data for hypothesis testing.

Other Relevant Developments—Independent Customer Product Stewardship Programs

As noted earlier, some customers have developed independent PSPs. These customers collect monitoring data as part of individual PSPs, and some share data with RCFC. One successful customer program is operated by Rex Materials Group (RMG). RMG operates three vacuum forming plants where RCF is used (the primary FJCs at these plants are mixing/forming, finishing, and auxiliary). RMG maintains a database of workplace exposure measurements dating back to 1997 that now contains more than 1000 TWA measurements as of 1 January 2007. These data have been collected by RMG using essentially the same protocol as is used by RCFC for the PSP 2002 program. This is clearly an ambitious monitoring program—and, coupled with initiatives to control exposures, one that pays dividends. Figure 19 shows a skyline chart comparing RMG's average TWA fiber concentrations at three RMG plants in three FJCs over the period from 2002 to 2006. As can be seen, RMG has managed to control fiber concentrations to levels beneath those for other customers in all but the auxiliary category at Plant Y. Again, provided the data are not overinterpreted, this exhibit suggests that further reductions in fiber concentrations among other customers might be feasible.

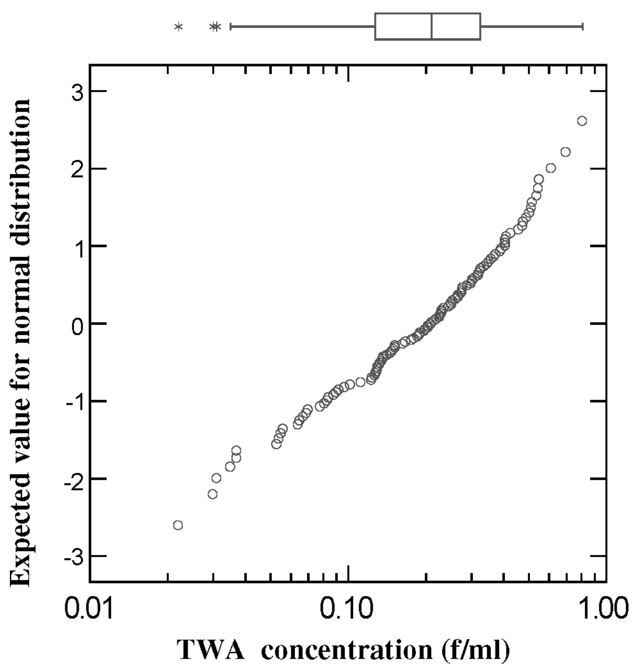

FIG. 18. Lognormal probability plot for TWA concentrations in the assembly category at an RCF manufacturing plant.

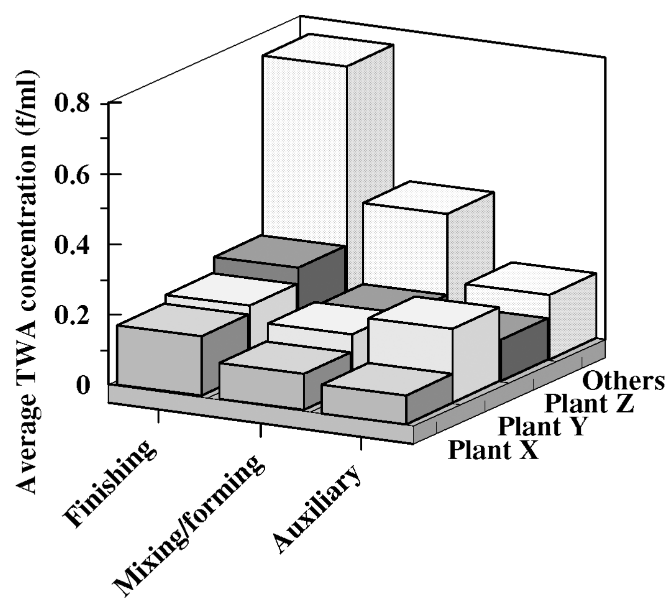

FIG. 19. Skyline chart comparing fiber concentration of RMG plants to the population of other customers (2002–2006).

RANDOM VERSUS FOCUSED SAMPLING

A basic design philosophy of the exposure monitoring program is that random sampling should be used for the historical baseline samples. Such a design enables statistically valid estimates and associated confidence intervals to be made for the entire workforce. This approach also enables "objective data" to be developed as used in OSHA rulemaking. However, for initial exposure screening or compliance verification purposes it may be more efficient to use purposive or focused samples. As noted by NIOSH (2006):

> When sampling to determine whether worker RCF exposures are below the REL, a focused sampling strategy may be more practical than a random sampling approach. A focused sampling strategy targets workers perceived to be exposed to the highest concentrations of a hazardous substance (Leidel and Busch 1994). This strategy is most efficient for identifying exposures above the REL if maximum-risk workers and time periods are accurately identified. (p. 3)

The advantage of focused sampling is that, providing that the hygienist's judgment is accurate, high-exposure jobs can be identified with substantially fewer samples than would be required with a random sampling plan. However, data collected using ad hoc sampling rules cannot be validly generalized to the entire worker population—another illustration of trade-offs in sampling design. Where resources permit, random sampling is to be preferred.

OUTREACH EFFORTS

One of the lessons learned early in the monitoring program is the need for an effective communications program. Communications products take a variety of forms, depending upon the intended audience and material to be covered. These products include:

- Practical workplace controls and handling guidelines that share information on control technology and other pertinent information. Reference to the RCFC web site (http://www.rcfc.net) or that of its counterpart in Europe (http://www.ecfia.org/en/frame2_en.html) provides examples of these products. Topics for these practical guidelines are selected based on measured exposures and the availability of improved control techniques. Illustrative titles include "Control of exposures to RCF during renovation of glass melting furnaces," "Guidance on obtaining respirators, fit testing, and employee training," "RCF finishing operations," "Batching of RCF," and "RCF after-service removal."
- Special "plain language" products to provide workers with relevant information on handling guidelines. Illustrated booklets, such as one titled "Working with Ceramic Fiber Products," are provided in a series of languages (including French, German, Portuguese, and Spanish). A training videotape was produced.
- "Help lines or hot-lines" are maintained by the RCFC member companies to provide real-time answers to customer inquiries.
- Material safety data sheets (MSDSs) provide information on possible hazards and risks associated with the handling and use of RCF.
- Articles are published periodically in peer-reviewed journals to share information.
- Training sessions are provided to customer employees—often in connection with monitoring visits by industrial hygienists, and
- Annual reports on the PSP are submitted to OSHA with copies of NIOSH and the U.S. EPA.

OSHA ACTIVITIES

Section 6(a) of the Occupational Safety and Health Act of 1970 directed the Secretary of Labor to promulgate permissible exposure limits (PELs) to promote occupational health and safety, which were to be based upon federal or national consensus standards. Section 6(b) of the Act set out the procedures for OSHA to follow in updating, revising and promulgating additional PELs. Recognizing that PELs could become outdated as new scientific evidence becomes available, OSHA instituted rulemaking efforts to update a large number of PELs.

In June, 1992, OSHA proposed to amend PELs for air contaminants in the construction, maritime and agricultural industries. In this notice, OSHA also proposed the addition of manmade mineral fibers, including RCF, to the Table Z list of air contaminants, with a proposed PEL of 1 f/cc (57 *Fed. Reg*. 26195–26202, covering the general industry as well), which was equivalent to the recommended exposure guideline (REG) adopted by RCFC in 1991. In proposing the 1 f/cc PEL, OSHA stated:

> OSHA is proposing a 1 f/cc 8-hour TWA limit for the respirable fibers of fibrous glass, including refractory ceramic fibers. OSHA preliminarily concludes that this limit will substantially reduce the significant risk of nonmalignant respiratory disease that exists in the absence of a limit for workers in all sectors...At this time OSHA believes it is premature for the Agency to reach a final decision on an exposure limit based on carcinogenicity. However, the proposed limit will also clearly increase the protection of workers from this effect as well. (p. 26, 202)

Prior to that proposal, there were no specific OSHA limits governing occupational exposures to refractory ceramic fiber, although RCF is subject to OSHA's 15 mg/m^3 (5 mg/m^3 respirable) 8-h TWA limit for total respirable dusts and particulates not otherwise regulated.

In 1992, the U.S. Court of Appeals for the Eleventh Circuit vacated and remanded the air contaminants rule for general industry. As a result of the court's decision, OSHA withdrew the proposed rule, including the proposed PEL for refractory ceramic fiber. RCFC's members supported the proposed PEL of 1 f/cc (at that time), and were disappointed in the court's decision and subsequent withdrawal of the proposal.

Subsequently, OSHA announced its proposed "Priority Planning Process" in August 1994. This system was designed to prioritize potential occupational safety and health concerns in order to target agency resources for standard setting. The results of OSHA's "Priority Planning Process" were announced on December 13, 1995. "Synthetic mineral fibers" was one of the substances identified by OSHA as a priority.

Regarding synthetic fibers, OSHA indicated that the agency "will work with business, labor, the professional community, and the states as partners to encourage worker protection without developing new rules at this time." In particular, OSHA endorsed "voluntary approaches [that] seek to correct workplace hazards through cooperative actions." OSHA also indicated that three different action approaches would be considered for the priorities not slated for rulemaking: (1) intervention approach, (2) voluntary approach, and (3) informational approach.

RCFC and its member companies approached OSHA and ended up working closely with the agency to formalize the existing PSP as a "voluntary approach," and in 2002, OSHA along with NIOSH endorsed a 5-year voluntary product stewardship program, called PSP 2002.

From OSHA's perspective the PSP has been and continues to be a successful joint effort. Under the PSP the RCFC developed data sheets, conducted training of its own members and conducted training of the downstream users of their product. Under the program, in addition to training, the coalition performs personal air monitoring on workers, develops training and information materials, and helps develop engineering and work practice controls. As most understand, OSHA standards are minimal requirements; under the PSP the impact on employee health and safety is considerably greater than if one were to solely apply the OSHA standards.

NIOSH ACTIVITIES

NIOSH was established when the U.S. Congress passed the Occupational Safety and Health Act of 1970 (Public Law 91-596), the same law that established OSHA. Through the act, Congress charged NIOSH with recommending occupational safety and health standards and describing exposure limits that are safe for various periods of employment. These limits include but are not limited to the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result of his or her work experience. By means of criteria documents and other policy statements, NIOSH communicates these recommended standards to regulatory agencies (including OSHA), health professionals in academic institutions, industry, organized labor, public interest groups, and others in the occupational safety and health community. Criteria documents contain a critical review of the scientific and technical information about the prevalence of hazards, the existence of safety and health risks, and the adequacy of control methods.

In support of its public and occupational health mission, NIOSH researchers began studying the potential health effects of airborne synthetic vitreous fibers in the early 1990s. This evaluation coincided with concerns about evidence of carcinogenicity observed in experimental inhalation studies with animals exposed to refractory ceramic fibers. Subsequent to this evidence further review of the human health data indicated health outcomes (pleural plaques and possibly decreased pulmonary function, as well as irritation of the skin and eyes) being reported in RCF manufacturing workers.

Initially, NIOSH researchers began reviewing the literature to prepare a Current Intelligence Bulletin for RCF to convey the potential risk of cancer for RCF exposed workers. As more information became available on the characterization of workplace exposures, a decision was made to prepare a more comprehensive criteria document that would contain an assessment of risk and recommendations for controlling occupational exposure. The culmination of this effort was the publication of the criteria document, entitled Criteria for a Recommended Standard: Occupational Exposure to Refractory Ceramic Fibers (NIOSH, 2006).

During the course of developing this document, NIOSH consulted with researchers in industry (RCFC, Vacuum Formers Association), academia (University of Cincinnati), and other federal agencies (OSHA, U.S. EPA) in interpreting the health data and identifying research gaps. These interactions included discussions about development of the Product Stewardship Program (PSP) by the RCFC. The latest version of the PSP, which includes recommendations for reducing workplace exposures to RCFs and the medical surveillance of workers, was endorsed by OSHA and supported by NIOSH when it was formally established in 2002. NIOSH researchers also collaborated with the RCFC in characterizing workplace exposures and evaluating engineering controls to identify techniques that could reduce airborne fiber concentrations. These collaborations have resulted in multiple publications (Dunn et al., 2004; Lentz et al., 1999, 2000, 2003; MacKinnon et al., 2001) documenting workplace exposures to RCFs and describing techniques effective in reducing airborne fiber concentrations. NIOSH was also asked by the RCFC to assist with assessing worker training needs, specifically in the use of training intervention effectiveness. NIOSH also organized and coordinated at least two public forums (announced in the *Federal Register*) to discuss scientific issues, including the interpretation of toxicology and human health effects data, the characterization of workplace exposures, and the feasibility of controlling RCF in the workplace.

The NIOSH criteria document is derived from a comprehensive evaluation of human and animal health data associated with exposure to RCFs including reports of an increased incidence of mesotheliomas in hamsters and lung cancer in rats following the inhalation of RCFs. Studies of workers who manufacture RCFs have shown a positive association between increased exposure to RCFs and the development of pleural plaques, skin and eye irritation, and respiratory symptoms and conditions (including dyspnea, wheezing, and chronic cough). In addition, current and former RCF production workers have shown decrements in pulmonary function.

Based on the health evidence and the assessment of controlling workplace exposures, NIOSH proposed a recommended exposure limit (REL) for RCFs of 0.5 fiber per cubic centimeter (f/cm^3) of air as a time-weighted average (TWA) concentration for up to a 10-h work shift during a 40-h work week. The establishment of this REL was based on evidence that limiting airborne RCF exposures to this concentration will minimize the risk for lung cancer and irritation of the eyes and upper respiratory system and was achievable in most workplaces. NIOSH also recommended an action level (AL) of 0.25 f/cm^3 in the exposure monitoring strategy to help employers determine when workplace exposure concentrations are approaching the REL. To ensure that any residual risks are further reduced, NIOSH recommended that continued efforts should focus on reducing exposures to less than 0.2 f/cm^3. In addition, a strategy to minimize exposures and consequently reduce the risk of adverse health effects was recommended. This strategy described the implementation of a comprehensive safety and health program that included hazard communication, a respiratory protection program, smoking cessation efforts, and a medical monitoring program.

Over the period of time that NIOSH has performed research and RCFC has been implementing PSP measures, mean exposure concentrations in the RCF manufacturing industry have continued to decline. Lockey et al. (1998) reported results of a longitudinal study of the pulmonary function of RCF workers and concluded that "the decrease in RCF exposure levels over the last 10 years through engineering and work practice changes has reduced any detectable continued effect of RCF exposure."

Collaboration among government agencies (NIOSH, OSHA, and U.S. EPA) and the RCF industry in implementing a comprehensive safety and health initiative (RCFC PSP, 2002) has helped reduce occupational exposures to more than 31,000 workers in the United States and has served as a model for protecting other RCF workers in more than 12 countries worldwide.

CONCLUDING COMMENTS

This article covers only two components of the RCF industry's PSP; those related to exposure monitoring and control. As noted in the detailed discussion of results, there have been many useful lessons learned over the past 17 years. The RCF industry and its government partners have been pleased with the program results to date and (as noted) intend to continue this cooperative program for at least the next 5 years. The industry remains committed to "continuous improvement," data sharing, and open communication of results.

The lessons learned as part of this program, several of which are discussed in the body of this article, are likely to be useful for other industries seeking to measure and control occupational exposure to potentially toxic materials. Perhaps the most important lesson to be learned is the need for focus in stewardship programs. The list of possible areas where stewardship might be necessary or valuable is long indeed; see, for example, the scope of the exemplary Responsible Care initiative of the International Council of Chemical Associations. To achieve meaningful progress, however, it is essential to prioritize stewardship activities. In the case of RCF the key health and safety concern is the risk associated with occupational exposure, and this realization has enabled the industry to focus stewardship resources on the measurement and control of this risk. Even if it turns out that this risk is very small, "less is better" in terms of exposure, and these efforts will not have been wasted.

Another important lesson learned by the RCF industry is that there are many benefits to partnering with government agencies. Voluntary initiatives can be a successful and cost-effective alternative to regulation and, as noted, many of the useful ideas and insights developed as part of this program have evolved from observations, suggestions, and comments of government personnel. Ultimately, cooperation is greatly superior to confrontation.

NOTES

1. Data fields refer to data or other information that is captured as part of the monitoring process. At present, there are approximately 70 data fields. In addition to the obvious fields that relate to fiber concentrations, there are important ancillary fields that describe the type of product used, FJC, job title, tasks being performed, plant identity, worker name, industry segment, observed engineering controls, and use of personal protective equipment (e.g., model and APF of respirator). There are also free text fields for various comments of the hygienists.
2. Specifically the agency wrote: "EPA is particularly encouraged by the commitment of RCFC to monitor workplace exposures to RCFs, and to look for ways to reduce exposures. EPA believes that such a program is a significant step towards the reduction in the risk of RCFs."
3. First-tier customers are those who purchased RCF directly from RCF producers. Some customers are distributors who resell RCF to typically smaller users. The industry has tried to sample these "customers of customers," but has had only limited success.
4. A Neyman allocation (see Cochran, 1977) was used as a point of departure in setting collection budgets for each FJC. This was modified in order to ensure adequate power for discrimination among certain FJCs and to reflect practical considerations in data collection. Definitions of the various FJCs are presented in Maxim et al. (1997).
5. This total does not include data collected in a parallel program among European RCF producers.
6. Where feasible, these are 8-h TWAs. Some activities, chiefly installation of furnace insulation or removal of after-service insulation, require fewer than 8 h to complete and actual TWAs are reported.
7. For example, in commenting on the Second Annual Report on the voluntary agreement with OSHA, Secretary Henshaw wrote: "Additionally, we would like to congratulate the RCFC, its member companies, and their customers on meeting or exceeding all of the Product Stewardship Program (PSP 2002) goals for 2003. These goals include the

reduction of exposures to refractory ceramic fibers in primary manufacturing, the increased use of respiratory protection, and the implementation of engineering controls. Your data demonstrate that you achieved these goals and we welcome the opportunity to continue our support of your efforts."

8. PSP-HTW stands for product stewardship program, high-temperature wools.
9. These data are maintained separately to avoid possible bias in estimates in the event that exposures at companies with separate monitoring programs have systematically different fiber concentrations.
10. TLA data can be very useful for the study of certain tasks within a shift. This monitoring program does collect data on TLAs as part of the overall program. However, these should not be confused with TWAs.
11. If the sampling periods for the task length averages were selected entirely at random, the distribution of task length averages would have the same mean as that for the TWA, but greater variability. However, samples are often taken at periods when some operation is being performed (and, therefore, concentrations are elevated) and not necessarily at random. In this event, the mean of the TLAs will be biased high. For toxicants with potentially chronic, rather than acute, health effects the appropriate metric would be a long-term average exposure.
12. It may strike some readers as surprising that there is not a greater difference between effective and measured exposures, given that the APFs for respirators are relatively high (e.g., 10, 50). The explanation is straightforward. The APF reduces exposures only for those workers who elect (or are required) to wear respirators. Not all workers wear respirators, and for these workers the measured and effective exposures are identical.

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