

FINAL REPORT
Epidemiology, 220-3W-05
Medical Department
3M Company
St. Paul, MN 55144

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Title: Descriptive Analysis of Serum Fluorochemical Concentrations from
Cottage Grove Employee Participants of the 2002 Medical Surveillance Program

Protocol Number: N/A
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ABSTRACT

In December 2002, 38 Cottage Grove employees voluntarily participated in the fluorochemical medical surveillance program. As part of this program, a blood sample was collected from each participating employee for the determination of two serum fluorochemicals: perfluorooctanoate (PFOA) and perfluorooctanesulfonate (PFOS). The serum PFOA concentrations ranged from 0.07 to 32.6 ppm with a mean (arithmetic) of 4.325 ppm (95% CI 2.025 - 6.624) and a geometric mean of 1.665 ppm (95% CI 1.019 - 2.720). Eleven participants' serum PFOA concentrations exceeded the Biologic Limit Value of 5 ppm for PFOA. Serum PFOS concentrations ranged from 0.050 to 1.170 ppm with a mean of 0.334 ppm (95% CI 0.245 - 0.422) and a geometric mean of 0.254 ppm (95% CI 0.198 - 0.327). The differences between the employees' 2002 PFOA and PFOS serum concentrations and their most recent prior measurements (collected since 2000) resulted in a mean decline of approximately 0.2 ppm for each compound. A cautious interpretation is warranted of any trend in serum concentrations because potential occupational exposure information was not incorporated in the analyses nor was time since last analysis.

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INTRODUCTION

In December 2002, the fluorochemical medical surveillance program was offered to employees at the 3M Cottage Grove (Minnesota) chemical manufacturing plant. Results have been reported elsewhere for previous fluorochemical medical surveillance programs at the Cottage Grove manufacturing plant (Gilliland and Mandel 1996; Olsen et al. 1998; 2000; 2003b) as well as the 3M Decatur (Alabama) (Olsen et al. 1999; 2001a; 2003a) and the 3M Antwerp (Belgium) fluorochemical manufacturing plants (Olsen et al. 1999; 2001b; 2003a). There were fewer participants in the 2002 Cottage Grove fluorochemical medical surveillance program than in previous examination years (1994, 1997, 2000) at this manufacturing site. This was likely due to the fact that the 2002 fluorochemical medical program was offered after the company's announcement to cease production of perfluorooctanyl-related materials, including perfluorooctanesulfonate and perfluorooctanoic acid (ammonium salt). The purpose of this study is to report the serum fluorochemical concentrations that were measured in 2002 and compare the participants' results with their most recent previous serum concentrations.

METHODS

The fluorochemical medical surveillance program is offered to employees at the Decatur manufacturing site on a periodic basis. Participation is voluntary. As part of the 2002 program, a blood sample was collected from each participating employee for determination of two serum fluorochemicals. These fluorochemicals were perfluorooctanoate (PFOA, $C_7F_{15}COO^-$) and perfluorooctanesulfonate (PFOS, $C_8F_{17}SO_3^-$).

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These two fluorochemicals were determined by high performance liquid chromatography electrospray tandem mass spectrometry methods (Hansen et al. 2001). Analyses were conducted at Tandem Labs (Salt Lake City, UT) using validated methods that have been reported elsewhere (Tandem Labs 1999; 2001a; 2001b). Fluorochemical concentrations were measured in $\mu\text{g/mL}$ and reported as parts per million (ppm).

RESULTS

The 38 Cottage Grove employee participants of the 2002 fluorochemical medical surveillance program had a distribution of serum PFOA and PFOS concentrations comparable to the results obtained from prior serum fluorochemical assessments for this manufacturing facility (Olsen et al. 2000; 2003c). Several subjects have contributed to multiple reports.

Serum PFOA concentrations ranged from 0.070 to 32.6 ppm (Figure 1) with a mean (arithmetic) of 4.325 ppm (95% CI 2.025 - 6.624). Because the concentrations were skewed, a geometric mean was also calculated for PFOA (1.665 ppm, 95% CI 1.019 - 2.720) which was comparable to the median value of 1.6 ppm. Twenty-six participants had a prior serum PFOA concentration (analyzed since 2000) whose mean was 6.255 ppm (95% CI 2.965 - 9.545) and median 3.345 ppm (Figure 2). Their mean 2002 serum PFOA concentration was 6.056 ppm (95% CI 2.87 - 9.249) and median was 3.180 ppm. The mean difference was a decline of (-) 0.199 ppm PFOA [95% CI (-0.629) - 0.231, $p < .18$].

The 38 participants had serum PFOS concentrations ranging from 0.050 to 1.170 ppm (Figure 3) with a mean of 0.334 ppm (95% CI 0.245 - 0.422) and a geometric mean

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of 0.254 ppm (95% CI 0.198 - 0.327). The median PFOS value was 0.280 ppm. Twenty-two participants had a recent, prior serum PFOS concentration (analyzed since 2000) (Figure 4) whose mean was 0.616 ppm (95% CI 0.352 - 0.880) and median was 0.390 ppm. These 22 employees' mean 2002 serum PFOA concentration was 0.423 ppm (95% CI 0.287 - 0.559) with a median value of 0.310 ppm. The mean difference between these 22 employees' 2002 PFOS concentration and their most recent prior PFOS concentration was a decline of (-) 0.193 ppm PFOS [95% CI (-0.351) - (-0.034), $p < .01$].

DISCUSSION

Because potential exposure to PFOA as well as perfluorooctanesulfonyl fluoride (POSF)-related materials occurred between the prior fluorochemical medical surveillance program (2000) and the present one, it is not possible to determine whether the modest decline in serum PFOA and PFOS concentrations is the result of serum elimination and/or reduced opportunity for potential workplace exposure. An ongoing study is examining the serum half-life of elimination for PFOA and PFOS among 27 retirees followed for 5 years at the Decatur and Cottage Grove manufacturing sites. Results from this investigation should be available in 2004. Presently, the estimated serum half-life of elimination for PFOA and PFOS are 4.4 years (SD = 3.5) and 8.7 years (SD = 6.1) respectively (Burris et al. 2002). These estimates, however, are based on only 9 of these retirees followed for 18 months.

Eleven participants had serum PFOA concentrations that were greater than the Biologic Limit Value (BLV). The purpose for the PFOA BLV program is explained, in detail, elsewhere (3M Company 2001). Basically, 3M established the BLV (5 ppm serum

PFOA) to represent the best estimate of a level of a chemical substance or its metabolite in a biological fluid that if present, even on a chronic basis, would not be expected to pose, or correlate with, a significant risk of adverse health effects to the worker(s). By establishing this BLV at 5 ppm for PFOA, the 3M exposure guideline committee did not intend to imply that serum levels of PFOA greater than the BLV immediately impose a significant risk of adverse health effects. However, if an employee's serum PFOA level either meets or exceeds the BLV, it should be understood that corrective actions (which may include temporary removal from the immediate work area) may need to be applied, on a case-by-case basis, at the direction of 3M Corporate Occupational Medicine.

Implementation of the BLV program by 3M Corporate Occupational Medicine did not allow for employees with serum PFOA concentrations ≥ 10 ppm to be directly engaged in the production of PFOA (Olsen et al. 2003c). Cottage Grove employees' serum PFOA concentrations have not been associated with adverse hepatic clinical chemistry enzymes, cholesterol, lipoproteins, plasma cholecystokinin, reproductive hormones or thyroid hormones (Gilliland and Mandel 1996; Olsen et al. 1998; 2000; 2003c).

There are several limitations to the analyses presented in this report. The results arise from a small subset of employees who voluntarily participated in the 2002 Cottage Grove fluorochemical medical surveillance program. The number of employees in the 2002 fluorochemical medical surveillance program is 75 percent less than those who participated in the 2000 fluorochemical medical surveillance program. Attrition of employees due to production cessation of PFOA and POSF-related materials occurred between 2000 and 2002. Unlike the 2000 Cottage Grove fluorochemical medical surveillance program, employee interview data were not collected in 2002 to provide an

estimate of exposure to POSF-related production areas for these workers. Therefore, it was not possible to associate serum fluorochemical concentrations to potential workplace exposures in the 2000-2002 time period. Knowledge regarding the serum elimination half-life of these fluorochemicals remains sparse. Actual time was not taken into account in the comparison of the most recent prior test results compared to the 2002 serum fluorochemical measurements. As a consequence of these limitations, there needs to be cautious interpretation of any trend analysis of the serum fluorochemical concentrations of the 38 Cottage Grove employees who participated in the 2002 fluorochemical medical surveillance program.

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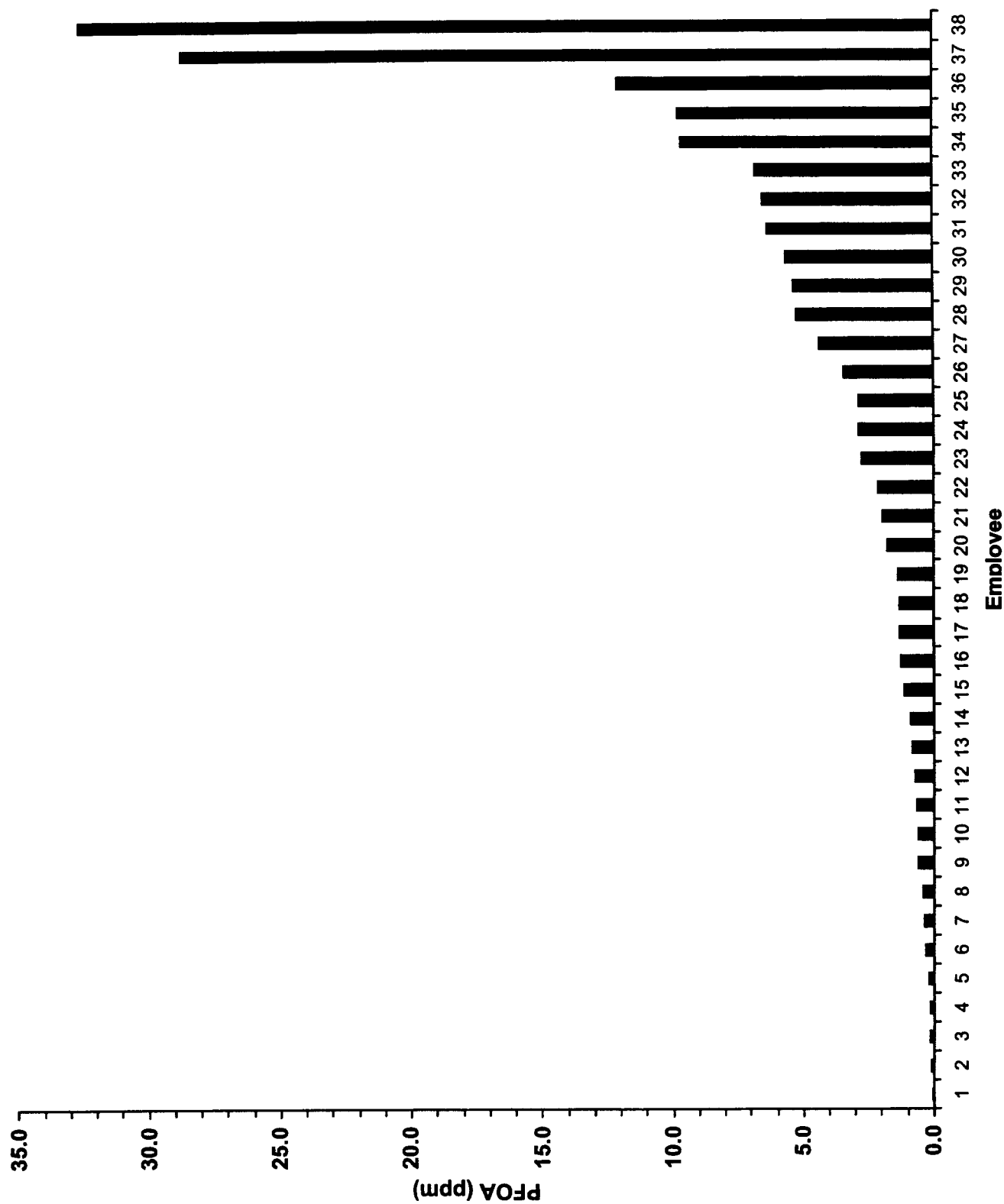
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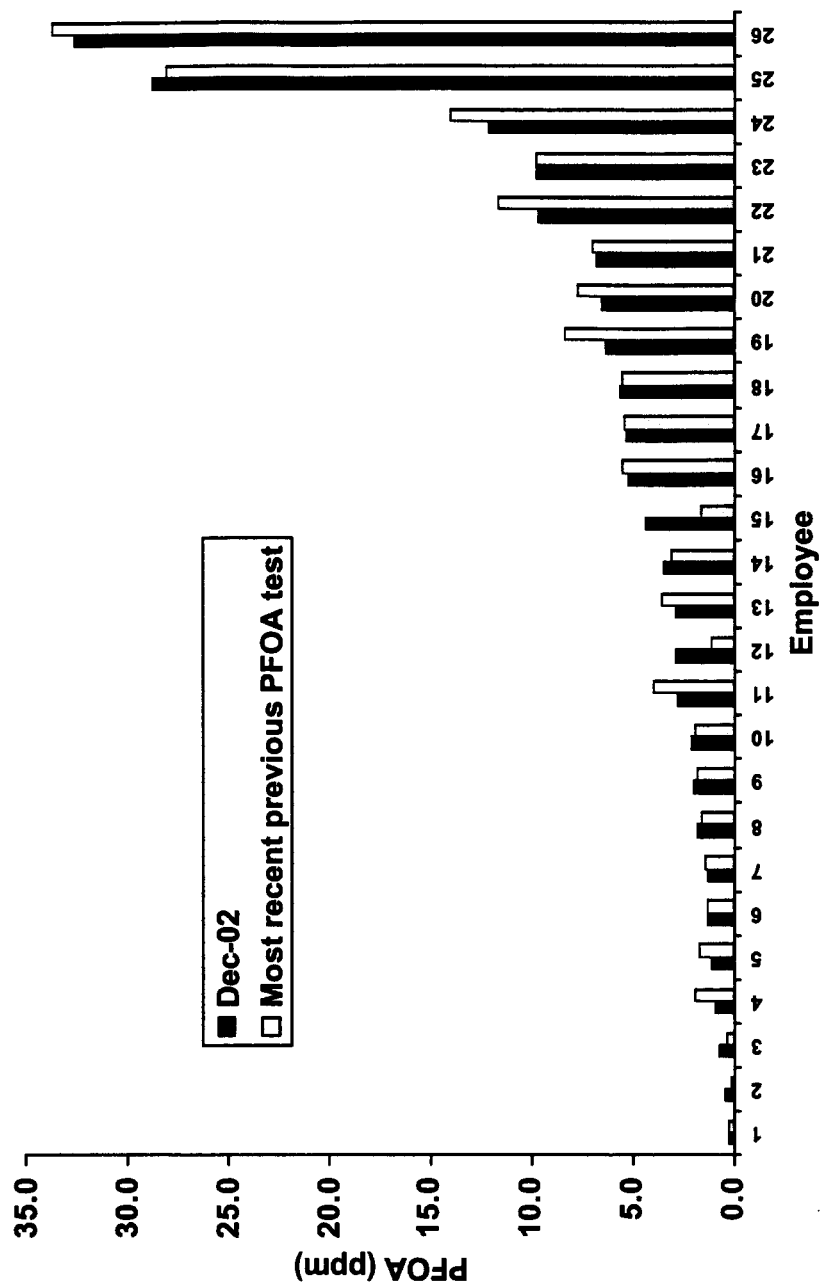
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**Figure 1. Cottage Grove Fluorochemical Medical Surveillance,
PFOA Concentrations, N = 38 Employees, December 2002**



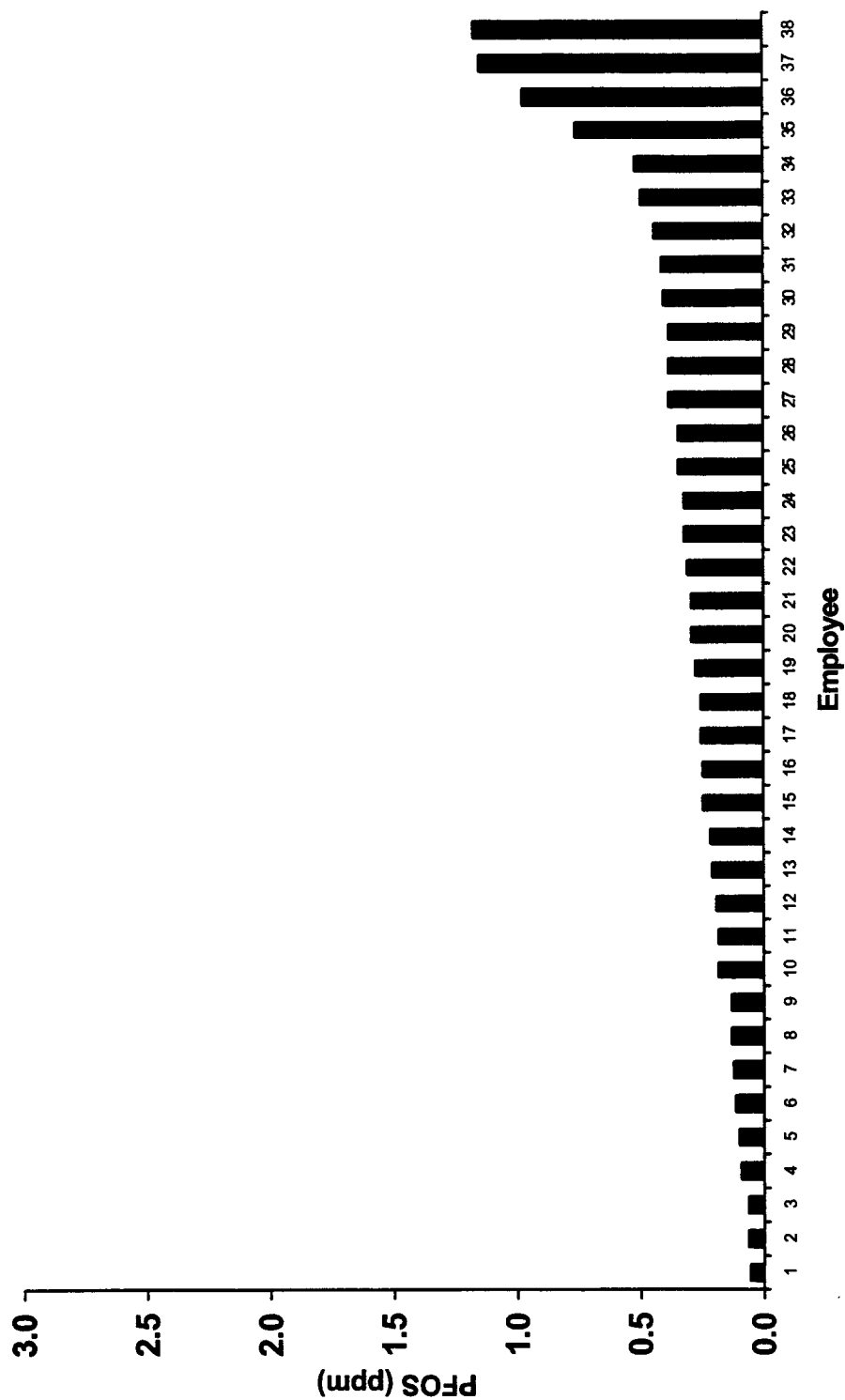
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Figure 2. Comparison of PFOA Concentraions for Those Employees (n = 26) who had A Most Recent Previous Test



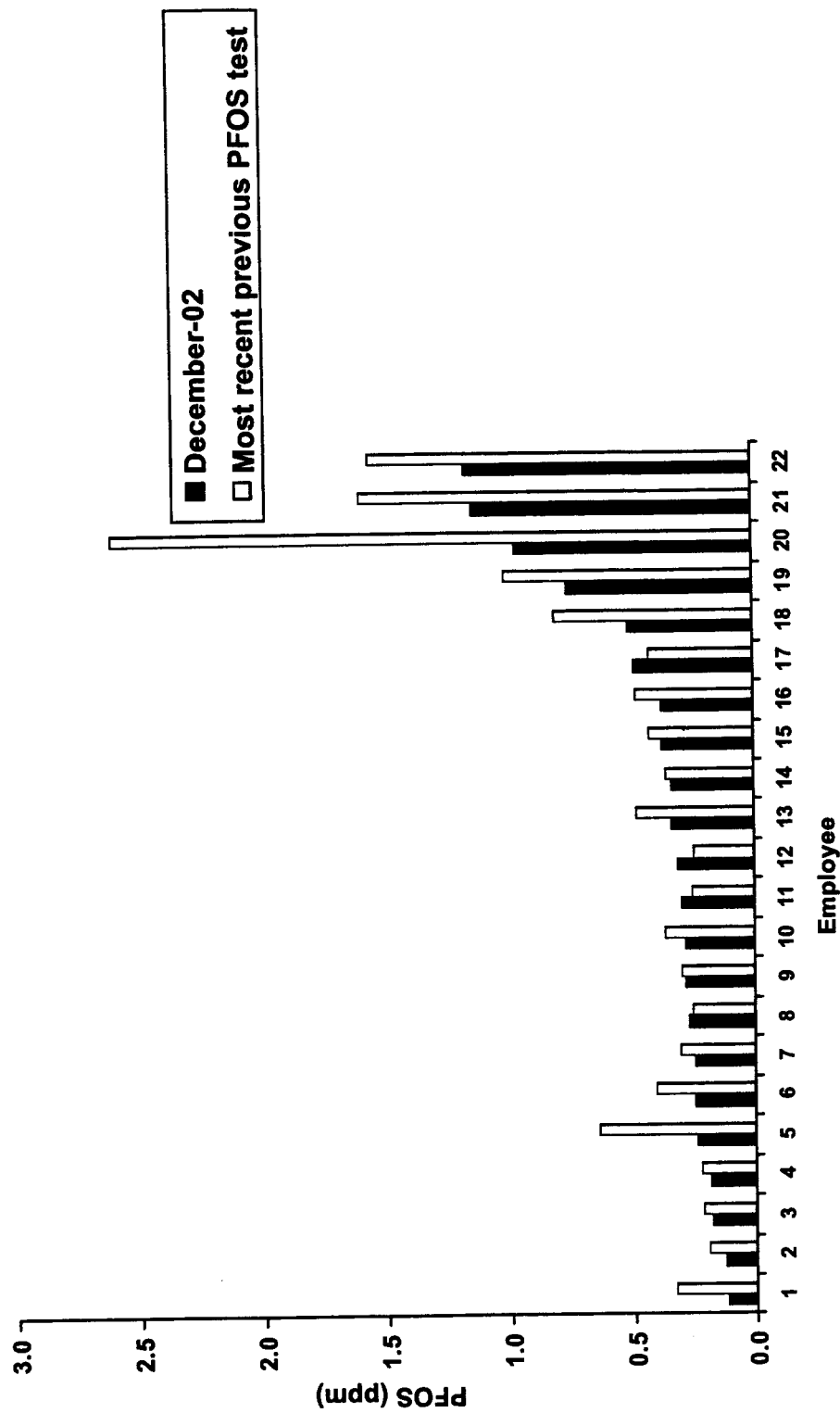
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**Figure 3. Cottage Grove Fluorochemical Medical Surveillance, PFOS Concentrations,
N = 38 Employees, December 2002**



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**Figure 4. Comparison of PFOS Concentrations for Those Employees
who had Most Recent Previous Tests (N = 22)**



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