Environmental Health Practice: Statistically Based Performance Measurement

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Objectives. State environmental and health protection agencies have traditionally relied on a facility-by-facility inspection-enforcement paradigm to achieve compliance with government regulations. We evaluated the effectiveness of a new approach that uses a self-certification random sampling design.

Methods. Comprehensive environmental and occupational health data from a 3-year statewide industry self-certification initiative were collected from representative automotive refinishing facilities located in Rhode Island. Statistical comparisons between baseline and postintervention data facilitated a quantitative evaluation of statewide performance.

Results. The analysis of field data collected from 82 randomly selected automotive refinishing facilities showed statistically significant improvements ($P<.05$, Fisher exact test) in 4 major performance categories: occupational health and safety, air pollution control, hazardous waste management, and wastewater discharge. Statistical significance was also shown when a modified Bonferroni adjustment for multiple comparisons was performed.

Conclusions. Our findings suggest that the new self-certification approach to environmental and worker protection is effective and can be used as an adjunct to further enhance state and federal enforcement programs. (*Am J Public Health.* 2007;97:819–824. doi:10.2105/AJPH.2006.088021)

Interest in the use of statistical measures to evaluate the effectiveness of environmental and human health protection programs has increased sharply in recent years. In 3 consecutive grant rounds (ending with the 2006 solicitation), for example, the US Environmental Protection Agency's National Center for Environmental Innovation awarded competitive grants to 14 states for the development of pilot and large-scale performance measurement–based initiatives modeled after the Massachusetts Environmental Results Program (ERP).[1,2] This industry self-certification approach is viewed as a simple and efficient way to control chemical hazards and environmental releases. The program accommodates both multimedia pollution (air, water, and hazardous waste, for example) and occupational health issues and reaches a larger segment of the regulated community than traditional enforcement programs. The US Environmental Protection Agency describes the model in this way:

> The Environmental Results Program combines compliance assistance, self-audit/certification, and statistically based inspections and performance measurement in order to strengthen or replace an existing regulatory structure. . . . [R]egulators educate facilities about their environmental impacts and obligations, as well as voluntary best practices they can use to alleviate potential impacts. Facilities are then required to self-evaluate and certify compliance. By conducting "before and after" inspections and applying statistical analysis, regulators can leverage limited inspection and enforcement resources to verify compliance, measure performance, and institute lasting improvements.[3]

The objectives of our study were to (1) evaluate the statistically based performance measurement component of the model, and (2) assess the overall effectiveness of the approach in a small-business industry sector that is characterized by a range of human health and environmental risks (the automotive refinishing industry). By using analytic techniques that follow accepted statistical theory and epidemiological practice, we show how state environmental health protection agencies can enhance accountability and inform programmatic decisionmaking through the collection and analysis of quantitative data on industry performance.

In practice, the model proceeds in a sequential manner: (1) baseline inspections document industry conditions before the program launch, (2) industry sector-wide program implementation (i.e., self-certification and government-sponsored technical and compliance assistance), and (3) postintervention facility audits coupled with performance measurement over a defined time interval. Compliance performance continues to be tracked and data are analyzed longitudinally for trends. A key aspect of this approach is that, with proper program design and rigorous data evaluation, only a sample set of field inspections are needed to obtain statistically valid results for industry performance. This approach is currently being applied by state agencies to several US industry sectors, including confined animal feeding operations, lithographic and screen printing, dry cleaning, photo processing, automotive refinishing and repair, and gasoline service stations. State agency experience suggests that the model is broadly applicable and may be used to address other US and international public health issues such as the control of infectious diseases (e.g., health department food protection programs), biological waste treatment, and low-level radioactive waste storage operations.

AUTOMOTIVE REFINISHING

An estimated 48 730 automotive refinishing facilities, employing 197 965 technicians, engage in collision repair nationwide.[4] Most of these shops have an annual sales volume of less than US$1 million and operate with varying degrees of technological sophistication; they can generally be characterized as forming a small, nonunion independent business sector.[4]

Occupational and environmental health research conducted in the automotive refinishing sector has shown a significant potential for workplace exposures to and environmental releases of various toxicants, including isocyanate aerosols, welding fumes and gases, metal-bearing particulates, silica and nuisance dusts, and chemical vapors.[5,6] The National Institute for Occupational Safety and Health as well as the International Agency for Research on Cancer reported on the potential for adverse health effects (including cancer, asthma, kidney disease, and central nervous system effects) among painters who are exposed to toxicants on the job.[7]

In 2003, after more than 2 years of industry research and stakeholder meetings to consider the hazards inherent in automotive refinishing as well as the economic and technical limits of individual facilities, the Rhode Island Department of Environmental Management (RIDEM)—in partnership with the Rhode Island Department of Health and the University of Rhode Island—launched a voluntary statewide certification program to improve regulatory compliance with both environmental and occupational health standards. This comprehensive certification program was designed to address worker training requirements, hazardous waste management, air quality, health and safety, and wastewater discharge among 367 licensed refinishing facilities located in Rhode Island. Demographically, the average Rhode Island automotive refinishing shop employed 5 people, processed 7 vehicles per week, and was composed of mostly White men who had a high-school education.[7]

METHODS

Self-certification initiatives typically collect binary, count, and descriptive data that are submitted in the form of questionnaire responses and corrective action plans, and collected during independent baseline and postintervention facility audits conducted by state agency staff. Corrective action plans are written summaries submitted to a state agency that indicate the amount of time needed (but not greater than a specified limit) to come into compliance with any single regulatory requirement. Industry participation rate, self-certification response, and corrective action plan data are then followed prospectively for performance trends.

To quantitatively assess whether an improvement in industry-wide performance occurred, data were collected from a statistically predetermined number of randomly selected facilities, which had been inspected at baseline and postintervention, and were compared and subjected to statistical analysis.

Determining Sample Size, Power, Significance, and Proportions

The following equation[8] was used to determine the total number of baseline and postintervention field audits needed to compare binomial proportions for assessing overall performance:

$$(1)\quad n = 2\left(\frac{Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} + Z_{1-\alpha}\sqrt{2\bar{P}(1-\bar{P})}}{\Delta} \right)^2$$

where P_1=baseline compliance rate, P_2=postimplementation compliance rate, $\Delta = |P_1 - P_2|$, $Z_{1-\alpha}$=significance level test statistic, $Z_{1-\beta}$=power test statistic, and $\bar{P} = (P_1 + P_2)/2$.

In Equation 1, sample size is determined on the basis of an assumed difference between 2 proportions: the compliance rates before (P_1) and after (P_2) program implementation:

$$(2)\quad P_1 = \text{assumed baseline compliance rate} = \frac{\text{no. shops in compliance}}{\text{total number of shops}}$$

$$(3)\quad P_2 = \text{assumed compliance rate postimplementation} = \frac{\text{no. shops in compliance}}{\text{total number of shops}}$$

The objective of the calculation was to obtain 2 samples (1 pre- and 1 postintervention) of sufficient size to allow the detection of a difference (i.e., an improvement) in compliance rates if one truly existed. To calculate total sample size for baseline and postintervention inspections, compliance rate proportions (P_1 and P_2), significance level, and power had to be prespecified. We chose the conventional significant (α) level of 5% and power of 80%. On the basis of previous field experience, we estimated the industry's mean baseline performance (P_1)—relative to all environmental as well as health and safety requirements—to be 40% and assumed a postintervention improvement of 25%. With these choices (where P_1=0.40, P_2=0.65, power=0.80 [$Z_{0.80}$=0.842], α=.05 [$Z_{0.95}$=1.645]), the total sample size required was calculated as

$$(4)\quad n = 2\left(\frac{0.842\sqrt{0.24+0.2275} + 1.645\sqrt{2 \times 0.525 \times 0.475}}{|0.4-0.65|} \right)^2$$

or approximately 97 (97/2 or 49 baseline plus 49 postintervention audits).

Choosing different values for P_1, P_2, α, and power resulted in different sample size estimates. In order to detect a smaller effect size (difference between proportions P_1 and P_2), larger samples were needed. The actual sample sizes we used were n_1=40 for baseline audits and n_2=42 for postintervention audits. Pre- and postintervention audits were conducted on independent cohorts that were randomly drawn from the entire universe of 367 licensed refinishing facilities.

Data Collection

Field data were collected during pre- and postintervention facility audits. Research Randomizer (Wesleyan University, Middletown, Conn), a computer-based random number generator, was used to select shops for inclusion in the study. After 40 baseline audits were completed, the auto body initiative was launched at an industry-wide workshop that was followed by a statewide mailing of self-certification checklists and guidance manuals. During baseline audits, technical assistance was offered regarding regulatory interpretation, compliance methods, and engineering and pollution prevention recommendations. A 6-month interval was then allowed for facilities to conduct self-evaluations and submit completed checklist and corrective action plan data to RIDEM. During this interval, project partners provided more than 25 on-site worker health and safety audits (conducted by the Rhode Island Department of Health), 10 university-led pollution prevention assessments, numerous telephone consultations, and multiple statewide workshops that reached more than 200 individuals. Incentives to participate in the program included reduced inspection priority for certified shops, the ability to correct violations without gravity-based penalties, advanced preparation for environmental and worker health and safety enforcement inspections (e.g., complaint based), no-cost technical and compliance assistance, and

TABLE 1—Methylene Chloride (MeCl) 2 x 2 Table

Intervention	MeCl +	MeCl –	Observed Data Set
Postintervention	a	b	r_1
Preintervention	c	d	r_2
	s_1	s_2	N

Note. *P* value for the test = Probability of observed data set + Probabilities of extreme data sets. Probability of observed data set = $r_1!r_2!s_1!s_2!$ / N!a!b!c!d!. Probabilities of extreme data sets computed by rearrangement of observed table values reducing "a" by 1 with fixed marginals.

TABLE 2—Automotive Refinishing Facility Baseline and Postintervention Compliance Performance Comparisons for Each Performance Indicator

	Baseline		Postintervention		Statistical Comparison	
	Sample Size n_1	Proportion p_1	Sample Size n_2	Proportion p_2	Percentage change[a] (95% CI[b])	P^c
Hazardous waste management						
Authorized agents	40	0.28	43	0.44	16 (. . .)	.088
Container inspections	16	0.06	9	0.22	16	.287
Container labeling	39	0.21	44	0.39	18 (. . .)	.059
Contingency plans	16	0.06	9	0.22	16	.287
EPA identification number	32	0.88	44	0.86	–2 (. . .)	. . .
Personnel training records	16	0.06	9	0.22	16	.287
Secondary containment	16	0.63	9	0.56	–7 (. . .)	. . .
Manifest tracking	39	0.56	44	0.89	33 (15, 51)	.001*
Air pollution control						
Compliant surface coatings	40	1.00	40	1.00	0 (. . .)	. . .
Dust control	39	0.33	40	0.48	15 (. . .)	.146
Enclosed spray gun cleaner	40	0.83	41	0.88	5 (. . .)	.360
HVLP spray equipment	40	1.00	40	1.00	0 (. . .)	. . .
Methylene chloride usage	40	0.67	41	0.95	28 (12, 44)	.001*
Solvent rag storage	36	0.81	41	0.88	7 (. . .)	.287
Ventilated sanding equipment	39	0.31	40	0.30	–1 (. . .)	. . .
Wastewater discharge						
Discharge signage	39	0.00	42	0.48	48 (33, 63)	<.001*
Unpermitted floor drains	40	0.67	39	0.69	2 (. . .)	.531
Washwater runoff	38	0.37	42	0.74	37 (17, 57)	.001*
Worker health and safety						
Employee medical examination	33	0.33	35	0.46	13 (. . .)	.214
Hazard communication program	32	0.28	37	0.46	18 (. . .)	.101
Lockout/tagout program	33	0.06	34	0.56	50 (31, 69)	<.001*
Personal protective equipment	33	0.09	38	0.63	54 (36, 72)	<.001*
Safety/health poster	36	0.42	40	0.83	41 (21, 61)	<.001*
Respiratory protection	30	0.33	38	0.61	28 (5, 51)	.023

Note. CI = confidence interval; EPA = Environmental Protection Agency; HVLP = high volume low pressure.
[a]Calculated as $100(p_2 - p_1)$.
[b]95% CIs calculated for indicators showing statistical significance at $\alpha = .05$; 95% CIs calculated as $(p_2 - p_1) \pm 1.96 \times$ square root $[p_1(1.00 - p_1) / n_1 + p_2(1.00 - p_2) / n_2]$.
[c]*P* values were calculated with the Fisher exact test online, available at http://home.clara.net/sisa/fisher.htm; *P* values calculated only for performance indicators showing improvement (1-tailed test).
*$P \leq .001$; Simes-modified Bonferroni adjustment for multiple comparisons.

the reduced environmental and worker liability associated with facility improvements.

Hypothesis Testing

To test whether performance had improved during the first-round interval of the program, the Fisher exact probability test (1-tailed) was used because observed cell frequencies in the 2×2 table (Table 1) were relatively small. For example, to determine whether the ERP initiative was successful at reducing methylene chloride usage among auto body shops, the following hypotheses were tested using the Fisher exact method,[9] where H_o=no difference in the proportion of shops using methylene chloride at baseline and postintervention and H_a=reduction in the usage of methylene chloride postintervention.

For the methylene chloride usage compliance performance indicator, shops were advised to stop using methylene chloride-based paint strippers. All other hypotheses tested were similar: H_o=no difference in the proportion of shops in compliance with a specific indicator (Table 2) at baseline and postintervention, and H_a=improvement in compliance postintervention. Written guidance and technical assistance were provided to specifically address each area where compliance improvement was being sought.

The Fisher exact test was used to calculate *P* values for each performance indicator. Although a test for multiple comparisons was also performed, discussions of performance improvements are generally on the basis of significance tests performed with the type I error fixed at .05 for each indicator.[10]

Test for Multiple Comparisons

In addition to checking each *P* value against the nominal level of significance of .05 to determine which indicators showed improvement, a modified Bonferroni adjustment[11] was used to avoid inflation of the overall type I error rate. The approach was to order the *P* values from the smallest to the largest. If the number of indicators was k, then the smallest *P* value was compared against .05/k, the next smallest *P* value was compared against .05/(k–1), and so on until the largest *P* value was compared against .05. This method is less conservative than the usual Bonferroni adjustment and has higher power.

RESULTS

Of 367 licensed refinishing facilities, 171 individual shops voluntarily certified to their performance and an additional 15 filed nonapplicability statements (valid Rhode Island Department of Business Regulation auto refinishing licenses were held, but the work was subcontracted out). Among these 171 facilities, 74 (43%) filed 271 individual corrective action plans along with their completed self-certification checklists.

Using Equation 1 and the set of assumptions specified in the Methods section, we estimated the total number (n) of shops needed in each sample to be 49. In order to estimate the industry's baseline performance, 51 auto body shops were randomly selected from a population of 367 licensees. Of the original 51 shops targeted for on-site visits, 40 baseline audits were ultimately conducted by RIDEM nonregulatory staff (3 shops refused entry, 1 was out of business, and 7 did not perform refinishing on site).

Baseline audit results are presented in Table 2. These data show that although 40 baseline audits were conducted, selected performance indicators often applied to less than 40 shops. For example, certain hazardous waste management requirements did not apply to shops that only engaged in satellite accumulation (i.e., storing <55 gallons of hazardous waste near the point of generation). This exclusion applied to performance indicators "container inspections," "contingency plans," "personnel training records," and "secondary containment" where $n_1=16$. Similarly, federal Occupational Safety and Health Administration (OSHA) requirements did not apply to 1-person owner-operated shops, which resulted in $n_1<40$ for all 6 "worker health and safety" indicators.

Table 2 shows the proportion of shops that were in compliance with each indicator at baseline. Performance estimates ranged from poor (0.00 or 0 out of 39 shops with signage posted over facility sinks prohibiting the discharge of chemicals) to excellent (1.00 or 40 out of 40 shops used compliant coatings and high-volume low-pressure spray guns). The overall mean was 43%.

A combined total of 42 randomly selected post-ERP implementation facility audits of both certified (18) and noncertified (24) shops were conducted. RIDEM nonregulatory technical assistance staff conducted 18 audits from a universe of 171 certified facilities (access to 2 additional shops could not be gained); enforcement personnel performed 24 regulatory inspections drawn from a pool of 196 noncertified shops. Although technical assistance staff gained access to only 18 of the 20 randomly selected certified facilities, data for all 20 shops were included in the Fisher exact test calculations because corrective action statements acknowledging regulatory deficiencies were submitted to RIDEM and were assumed to be accurate indicators of nonperformance for statistical analysis purposes.

The total number of auto body shops that were inspected, and to which the specified performance indicator was found to apply, is given in Table 2. Compliance rate proportions resulting from all postintervention facility inspections are presented in column p_2 and ranged from 0.22 (compliance with required weekly hazardous waste "Container inspections" and the maintenance of appropriate "Personnel training records") to 1.00 (the use of "Compliant coatings" and "HVLP spray equipment"). During the time between baseline and postintervention audits, staff from the Rhode Island Department of Health conducted 72 voluntary health and safety audits. The audits detected 487 serious hazards, 73 other-than-serious hazards, 25 regulatory hazards, and 1 imminent danger hazard, all of which were corrected (the Department of Health maintains a policy that all OSHA violations discovered during nonregulatory site assessments must be corrected within a given time frame).

A total of 74 auto body shops (43%, 74 out of 171 ERP participants) filed 271 individual corrective action plans along with completed self-certification forms to RIDEM; the range was 1–37 plans per shop. Of these, 234 from 69 shops were found to be valid. Figure 1 shows the submissions to RIDEM by programmatic area: air, water, hazardous waste, and occupational health; subcategories for each of the 4 major divisions are also shown.

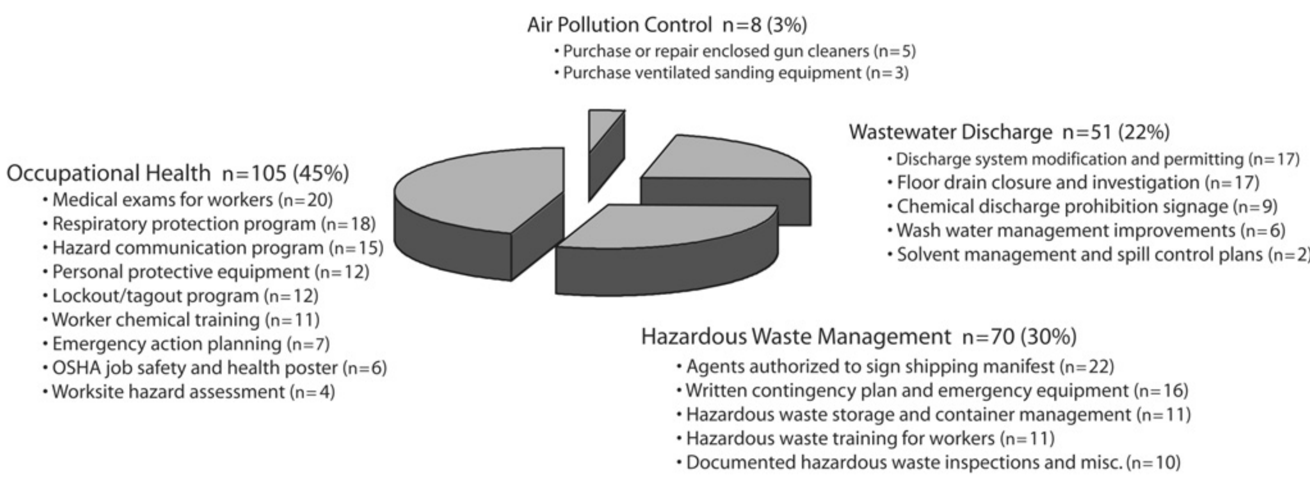

FIGURE 1—Number of corrective action plans received from 69 certified shops, organized by major category.

Performance Results and Statistically Significant Improvements

Percentage differences between postintervention and baseline proportions (p_2–p_1) are shown in Table 2. These differences ranged from a net decrease in performance of −7% (secondary spill containment for hazardous waste) to a 54% improvement in the use of personal protective equipment and a mean improvement of 22% for all nonnegative indicators.

To determine which performance measures achieved statistical significance, the Fisher exact test was applied to all indicators that showed a measurable improvement: *P* values for these 19 indicators are shown in Table 1. Confidence intervals were also calculated for 8 of the 19 indicators that showed significance at $\alpha < .05$. The Simes-modified Bonferroni adjustment for multiple comparisons reduced the number of statistically significant indicators from 8 to 7.

In general, our results showed at least 1 statistically significant improvement in each of the 4 major health and environmental categories. Although a number of statistically significant improvements were found, the level of confidence we placed in any single performance indicator varied. For example, a statistically significant indicator that had a large effect size where compliance was also directly observable (e.g., wastewater discharge signage posted directly over a facility sink [48%, $P < .01$] or displaying the OSHA-required Job Safety and Health Protection poster in an area where all employees could see it [41%, $P < .01$]) was interpreted to carry more weight than a statistically significant improvement for a multicomponent performance indicator for which individual program elements may not have been thoroughly verified by RIDEM inspectors (e.g., the OSHA requirement for a comprehensive workplace respiratory protection program [28%, $P < .03$]). In addition, no change in facility performance regarding the usage of high-volume low-pressure spray guns and compliant coatings provided a good indication that facilities were consistently complying with RIDEM requirements.

In other cases, even though statistical significance was not achieved, real improvements were found to occur as a result of the program. For example, OSHA requires that employees who are subject to the federal respiratory protection standard (e.g., professional spray painters) undergo an evaluation by a physician or other licensed health care professional and receive clearance to wear a respirator. Though the 13% improvement found during field inspections was not statistically significant ($P = .21$; Table 2), 20 of the 69 shops that submitted corrective action plans (i.e., self-reported noncompliance) documented that they were deficient relative to this regulatory requirement and that compliance would be achieved within 2 months. Overall, the number of corrective action plans submitted by the ERP-participating shops provided supporting evidence that facility owners made a real effort to improve compliance with environmental and health and safety regulatory requirements.

DISCUSSION

Rhode Island's experience confirms that self-certification programs can produce measurable and statistically significant improvements in environmental performance, as originally reported by the state of Massachusetts.[2] The statistical methods used to determine sample size and evaluate field inspection data highlighted the importance of the prespecified input parameters used in Equation 1; especially, the assumed mean level of baseline performance (P_1) and expected improvement or target effect size in compliance rate proportions. Statistically significant improvements in environmental performance, for example, were found only for those indicators that showed a difference between pre- and postintervention compliance rate proportions of 28% or more (Table 2), as assumed ($\Delta = |P_1 - P_2| = 0.25$; Equation 1) at the start of the program.

Before adopting the certification approach, we estimated that the 4 RIDEM divisions most responsible for regulatory compliance in the auto body sector (Office of Air Resources, Office of Waste Management, Office of Compliance and Inspection, and Office of Water Resources) collectively inspected fewer than 5% of all licensed facilities in any given year and most inspections were complaint driven. Inspection coverage by state and federal agencies responsible for occupational health and safety was thought to be about the same. After the traditional facility-by-facility inspection approach, on-site audits were largely single media in nature, that is, individual facility audits considered only air, water, hazardous waste, or occupational health issues at the time of inspection, but not all 4 simultaneously. The probability that an individual shop would receive a comprehensive, multimedia inspection in any given year was virtually zero. By comparison, the certification program achieved a 49% participation rate and comprehensive self-assessments addressed all major air, water, hazardous waste, pollution prevention, and occupational health and safety standards within 6 months. In addition, education and outreach materials (compliance workbook, self-audit checklist, and fact sheet mailings) were sent to 100% of all licensed facilities.

On the basis of the success of the automotive refinishing industry initiative, Rhode Island expanded the self-certification approach to exterior lead-based paint removal contractors, auto salvage yards, and underground storage tank sectors. To enhance implementation, Rhode Island also began to automate the field inspector data collection and statistical analysis components of these programs, starting with the underground storage tank sector. Automation included converting field inspection checklists into an electronic form and using tablet personal computers with up-loading capability for digital photos. Automation and expansion of the certification program makes it possible for the state to achieve broader compliance with fewer on-site inspections and improved efficiency.

Although a voluntary approach worked well for the Rhode Island automotive refinishing industry, this article reports on a program that was implemented with a great amount of interaction with all stakeholders, active program partners (including both the regulatory and academic sectors), all operating within a geographically compact state, which benefits from an ability to implement comprehensive programs with willing members of the regulated community. The success of voluntary initiatives may be limited in regions where these cofactors are not present. A number of specific factors contributed to the initial success of the program, including increased awareness within the industry of a coordinated enforcement effort in which nonparticipants would be subject to random regulatory inspections and extensive research and outreach activities conducted previous and subsequent to program kickoff.

In conclusion, the automotive refinishing case study demonstrates that voluntary compliance with human health and environmental standards can be quantitatively assessed by auditing a relatively small number of facilities both pre- and postintervention. Taken together, analysis of the random field-audit data, self-certification checklist submissions, and information provided in corrective action plans indicated that the program succeeded in improving compliance performance. As constructed, the self-certification approach is an iterative process by which modifications in guidance materials and checklists are made in response to regulatory changes, periodic industry self-assessments are conducted as required, and individual improvements in facility performance and higher industry-wide participation rates are continually sought. As with any traditional or nontraditional state-based environmental health initiative, however, the sustainability and long-term success of industry self-certification programs will depend upon adequate funding, agency stewardship, and organizational support. Finally, the results of this study should not be interpreted to mean that voluntary self-certification programs are an acceptable alternative to state and federal regulation, but rather that voluntary programs can be a useful adjunct that results in significant performance improvements when coupled with field inspections and strong enforcement. ■

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Contributors

R.T. Enander led the writing, data analysis, and oversaw project implementation with R.N. Gagnon who originated and co-designed the project. R.C. Hanumara guided and oversaw all statistical analyses. E. Park and T. Armstrong conducted field investigations, data collection, data management, and were instrumental in the project launch and implementation. D.M. Gute assisted with conceptualizing the original field study and contributed to the writing.

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Human Participant Protection

No protocol approval was needed for this study.

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