



## **PSP Compliance Principles**

In 2012 and 2013, OSHA brought actions seeking to enforce various provisions of the Product Stewardship Program (PSP) for refractory ceramic fibers (RCF) against a customer of one of the HTIW Coalition members. To the knowledge of the HTIW Coalition and its members, all such actions have been settled to date.

In an attempt to clarify PSP compliance issues for future reference, HTIW Coalition offers the following general principles for PSP compliance. All are based on current and longstanding OSHA regulations or policies. While these principles apply generally, HTIW Coalition recognizes that each specific case must be judged on its own merits.

**1. Applicable OSHA Standards.** First and foremost, nothing in the RCF PSP authorizes noncompliance with applicable Occupational Safety and Health Standards. In the enforcement proceedings referenced above, HTIW Coalition reaffirmed that the RCF PSP cannot supersede applicable OSHA standards, such as the standards governing respiratory protection (29 CFR 1910.134). Compliance with all applicable standards is required. However, as discussed further below, neither the RCF Recommended Exposure Guideline (REG) contained in the PSP nor the NIOSH



Recommended Exposure Limit (REL) for RCF, both of which have been established at 0.5 f/cc, are applicable OSHA standards.

**2. General Duty.** In the enforcement actions referenced above, OSHA citations have alleged that exceedance of the REG and REL, without installation of engineering controls thought by OSHA to be feasible, is a violation of the General Duty Clause.<sup>1</sup> However, it is important to remember that unlike an OSHA permissible exposure limit (PEL), neither the REG nor the REL have been determined to be necessary to prevent a significant workplace risk. Both are based primarily on determinations of the airborne concentration that is feasible to attain with engineering controls at most operations. Both HTIW Coalition and NIOSH believe that compliance with the 0.5 f/cc level will reduce whatever risk may be present. As NIOSH stated in the RCF Criteria Document:

At this time, the available health data do not provide sufficient evidence for deriving a precise health based occupational exposure limit to protect against lung cancer. However, given what is known from the animal and epidemiological data, NIOSH supports the intent of the PSP and concurs that a recommended exposure limit (REL) of 0.5 f/cm<sup>3</sup> as a TWA for up to a 10-hr work shift during a 40-hr workweek will lower the risk for developing lung cancer.<sup>2</sup>

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<sup>1</sup> The term “exceedance,” as used herein, refers to airborne concentrations above the REG or REL in the absence of proper respiratory protection. Airborne concentrations above the REG or REL would not constitute an exceedance if proper respiratory protection is used.

<sup>2</sup> See NIOSH, “Occupational Exposure to Refractory Ceramic Fibers, Criteria for a Recommended Standard,” pp. v-vi (May 2006).



However, neither the REG nor the REL are based on any determination that attainment is necessary to prevent a significant workplace health risk.

General Duty citations alleging exceedance of the REG or REL should be based on OSHA's Enforcement Policy for Respiratory Hazards Not Covered by OSHA Permissible Exposure Limits.<sup>3</sup> The Policy states that in cases where an OSHA PEL does not apply, OSHA will review other available occupational exposure references and recommendations. These include NIOSH RELs and manufacturers' recommendations such as the RCF REG.

As noted in the Policy, Section 5(a)(1) of the OSH Act requires each employer to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." When enforcing this requirement, the Occupational Safety and Health Review Commission and court precedent have determined that the following elements must be established in order for OSHA to prove a violation of the general duty clause:

1. The employer failed to keep the workplace free of a hazard to which employees of that employer were exposed;
  2. The hazard was recognized;
  3. The hazard was causing or was likely to cause death or serious physical harm;
- and,

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<sup>3</sup> Memorandum from Kimberly Stille to Regional Administrators re: Enforcement Policy for Respiratory Hazards Not Covered by OSHA Permissible Exposure Limits (November 2, 2018). The Policy is available at <https://www.osha.gov/laws-regs/standardinterpretations/2018-11-02>.



4. There was a feasible and useful method to correct the hazard.

In discussing these requirements, the Policy states:

When applying these elements to respiratory hazards, it is important for Area Directors to *ensure that 5(a)(1) citations are not based solely on evidence that a measured exposure exceeded a recommended occupational exposure limit (OEL), such as a Threshold Limit Value (TLV), or based on the fact that there is a documented exposure to a recognized carcinogen. Unless the case file evidence proves all four of the above elements, the Area Office should issue a hazard alert letter (HAL). The HAL should advise the employer that one or more employees at the establishment was being, or had been, exposed to a potentially serious respiratory hazard from a chemical that exceeded an OEL, and provide a series of recommended exposure control suggestions (p. 1, emphasis in original).*

The Policy also provides the following guidance for determining compliance with these elements when specifically applied to *respiratory* hazards:

- a. *The employer failed to keep the workplace free of a hazard to which employees of that employer were exposed* - The evidence should substantiate that regular and continuing employee exposure to the chemical at the measured levels could reasonably occur. However, if the exposed employees were wearing appropriate respiratory protection with no deficiencies in the respirator program, then the likelihood that OSHA could establish a respiratory hazard covered by the general duty clause would be low.
- b. *The hazard was recognized* - OSHA can establish this element in one of two ways. (1) For employer recognition: Evidence may include employee complaints



to management, illness and injury logs, consultant reports, a previous HAL, internal safety and health policies related to workplace operations involving the chemical that may refer to an OEL, or information from a manufacturer describing safety and health precautions for equipment or chemicals used in the workplace such as the chemical manufacturers' safety data sheet (SDS). (2) For industry recognition: Evidence may include an industry or trade association's guidance document, or an assessment from an industry expert describing the work practice or operation used at the establishment and explaining the particular health hazards and recommended control measures. Alternatively, a similar publication from a (non-OSHA) federal, state, or local government agency, or from a professional organization, may also provide good evidence.

- c. *The hazard was causing or was likely to cause death or serious physical harm -* Although an illness or injury from the measured exposure need not have occurred yet, the strongest evidence is an employee illness/injury, hospitalization, fatality, or medical diagnosis related to workplace exposure. In the absence of this, the evidence must include more than just the fact that a measured exposure exceeded a TLV or REL, because these recommended limits may be much lower than the level at which a serious health effect may be experienced. In most cases, proving this element will require an expert or



industry-related peer reviewed study to document that serious physical harm could occur at the measured level with continuing employee exposure. Additionally, establishing serious physical harm for some respiratory hazards may be particularly difficult if the resulting illness, such as cancer, would require a substantial period of time to occur.

- d. *There was a feasible and useful method to correct the hazard* - Evidence may include the SDS describing work practices for safe handling, engineering controls, and personal protective equipment, or published industry and/or NIOSH studies (e.g., health hazard evaluations (HHEs)) involving similar chemical processes or operations. Proving that feasible abatement measures would eliminate or materially reduce workplace exposure to a level that no longer presents a serious health hazard will likely require expert testimony.

The HTIW Coalition reiterates its commitment to achieve and maintain exposure levels at or beneath the REG and REL, both in plants operated by its member companies and those facilities operated by its customers. The Coalition maintains that attainment of these guidelines is feasible in most operations without respiratory protection and in all cases with appropriate respiratory protection. The HTIW Coalition has published relevant outreach material on appropriate engineering controls and workplace practices for handling RCF. As necessary HTIW Coalition members work



with customers to ensure that attainment of these guidelines is achieved. When presented with evidence to the contrary from customer monitoring or an OSHA inspection, the Coalition and its members will make this literature available to customers and offer suggestions for improvement to those facilities.

**3. Statistical Procedures.** In the enforcement matter referenced above, an issue arose regarding the statistical procedures for determining exceedance of the RCF REG and REL. Although the REG and REL are not applicable OSHA standards, exceedance of them should be determined using the statistical procedures specified in Section II, Chapter 1, Part IV.D. of the OSHA Technical Manual (OTM) as in effect on August 1, 2014. As the OTM recognizes, all sampling and analytical methods have some degree of uncertainty as a result of sampling and analytical error (SAE). The SAE is used to determine the upper and lower confidence limits of the sampling results, and is especially important when sample results are near the level of the REG. As discussed in the OTM:

Error factors determined by statistical methods shall be incorporated into the sample results to obtain the lowest value of the true exposure (with a stated degree of statistical confidence) and also the highest value of the true exposure (also with a stated degree of statistical confidence).

Confidence limits are values at each end of the confidence interval, which is the probable range of the true value. The lower value is called the lower confidence limit (LCL), and



the upper value is the upper confidence limit (UCL). The LCL and the UCL are each termed one-sided because the main concern is with being confident that the true exposure is either less or greater than the PEL.

OSHA applies the LCL and UCL with a 95% statistical confidence limit and they are expressed here as  $LCL_{95\%}$  and  $UCL_{95\%}$ . SAEs that provide a one-sided 95% confidence limit have been developed and are reported out on the Air Sampling Report.

If the  $UCL_{95\%} < 1.0$ , a violation does not exist.

If  $LCL_{95\%} < 1.0$  and the  $UCL_{95\%} > 1.0$ , classify as possible overexposure.

If  $LCL_{95\%} > 1.0$ , a violation exists.<sup>4</sup>The OTM goes on to explain that the confidence limits are calculated differently depending on the type of sampling method used. With respect to results in the “possible overexposure” category, the OTM states:

If the results are in the "possible overexposure" category, consider further sampling, taking into consideration the seriousness of the hazard and pending citations. If further sampling is not conducted, or if additional measured exposures still fall into the "possible overexposure" category, the CSHO may wish to carefully explain to the employer and employee representative at the closing conference that the exposed employee(s) may be overexposed, but that there is insufficient data to document noncompliance. The employer should be encouraged to voluntarily reduce the exposure

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<sup>4</sup> Because the OTM is discussing compliance with PELs, the term “violation” is used. As discussed below the proper term with respect to the RCF REG or REL would be “exceedance,” because an exceedance is not a violation as with a PEL.





and/or to conduct further sampling to ensure that exposures are not in excess of the PEL.

In interpreting these principles and procedures it is important to note that “overexposure” related to effective exposure should consider the protective effect of respirators.

4. **Objective data.** In the final crystalline silica standard, OSHA defined objective data as follows:

“Objective data” means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer’s current operations. 81 Fed. Reg. 16710 (March 25, 2016).

The silica rule allows use of objective data for initial exposure assessments and various other purposes. As OSHA had noted in the silica proposal, OSHA has allowed employers to use objective data in lieu of initial monitoring in other standards, such as formaldehyde (29 CFR 1910.1048) and asbestos (29 CFR 1910.1001)(78 Fed. Reg. 56447). For example, the formaldehyde standard provides:

Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will



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1025 Connecticut Avenue, N.W. Suite 1000 c/o Verdant Law Firm Washington, DC 20036 tel 240-343-1738  
[www.htiwcoalition.org](http://www.htiwcoalition.org)

not be required to measure employee exposure to formaldehyde.

As discussed in the PSP, the HTIW Coalition member companies have systematically collected objective data on RCF workplace exposures for over 20 years, and now maintain a large and sophisticated database on exposures in virtually all affected job categories. Representatives of HTIW Coalition meet annually with OSHA (and other invitees) to discuss the latest data and exposure trends. In most if not all instances, the RCF data clearly meet the definition of objective data as proposed in the silica rule. In appropriate cases demonstrations of REG and REL attainment may be based on objective data as defined above.

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