

OSHA clarifies respirator selection for diisocyanates

By Larry Janssen, C.I.H.

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Introduction

The revised Occupational Safety and Health Administration (OSHA) respiratory protection regulation 29 CFR 1910.134 requires employers who use gas or vapor air-purifying respirators to develop cartridge change schedules based on objective information or data.⁽¹⁾ This provision applies whether or not the contaminant has adequate warning properties. OSHA says this very clearly in its compliance directive for 1910.134, which states, "Where an effective change schedule is implemented, air-purifying gas and vapor respirators may be used for hazardous chemicals, including those with few or no warning properties."⁽²⁾

While no chemicals are exempt from the regulation or the compliance directive, some users were still uncertain whether air-purifying respirators can be used for the common diisocyanates such as toluene-2,4-diisocyanate (TDI), hexamethylene-1,6-diisocyanate (HDI) and methylene bisphenyl isocyanate (MDI). OSHA has clarified its position on this issue in a letter dated July 18, 2000 that indicates air-purifying respirators may be used if all requirements of 1910.134 are met and other

potential hazards are addressed. The letter is available at <http://www.3M.com/occsafety/html/fregulations.html>

Discussion

Historically, supplied-air respirators have been used for exposures to the common diisocyanates. This was expected, since OSHA's original respiratory protection regulation used a decision logic that did not allow air-purifying respirators to be used for gases or vapors with poor warning properties. A contaminant is said to have adequate warning properties if it has persistent odor or irritation effects at concentrations at or below the exposure limit.⁽³⁾ Reported odor thresholds for the diisocyanates range from two to more than ten times their exposure limits.^(4,5) Therefore, the diisocyanates have poor warning properties.

If the revised respiratory protection regulation requires cartridge change schedules to be used instead of reliance on warning properties, why have some been concerned about the suitability of

air-purifying respirators for the diisocyanates? It seems that their concerns are based on one or more of four misconceptions:

Misconception #1

Air-purifying respirators should not be used because diisocyanates have poor warning properties. Although OSHA specifically permits change schedules *in lieu of* sensory warning properties, some argue this is not a safe practice. They believe diisocyanates could enter a facepiece through a spent cartridge or defect (e.g., a torn exhalation valve) and the user would be unaware, risking prolonged exposure. In reality, this potential exists for any gas or vapor with poor warning properties and for all

(see *Diisocyanates* on page 2)

Inside this issue

Volume 18 Number 2 2000

OSHA clarifies respirator selection for diisocyanates . . .	1-2, 4
<i>JobHealth Highlights</i> making transition to electronic format	3
New NIOSH policies support OSHA respirator standard	4-6
Saccharin removed from carcinogen list	5
3M™ Select Software® and 3M™ Service Life Software now integrated	7
3M OH&ESD announces training courses for 2001	8

particulate contaminants.

In addition, the fact that a contaminant has adequate warning properties does not ensure that all respirator users will be able to detect it at or below the exposure limit. Because odor thresholds are median values for a population, more than half of individuals will not detect the odor until the level is above the reported odor threshold.⁽³⁾ A sound respiratory protection program minimizes the risk of undetected exposure by assuring that respirators are properly fitted, maintained and worn, and that cartridges are changed at appropriate intervals.

Misconception #2

Air-purifying respirators cannot remove diisocyanates. In fact, it has been known for many years that diisocyanates are adsorbed by activated carbon and retained extremely well.^(6,7) Cartridge breakthrough equations predict very long service lives for the diisocyanates under plausible use conditions. If a diisocyanate is the only air contaminant present, a cartridge change schedule will most likely be based on general hygiene and maintenance considerations rather than breakthrough concerns. If other organic vapors are present in the same atmosphere as a diisocyanate, those vapors invariably break through first. Cartridge change schedules will be established using predicted breakthrough of the other contaminant(s).

It must be recognized that diisocyanates may form condensation aerosols when they are airborne. For this reason, it is generally necessary to use a particulate filter in combination with an organic vapor cartridge.

Misconception #3

Air-purifying respirators are not approved for gases and vapors with poor warning properties. The National Institute for Occupational Safety and Health (NIOSH) supports OSHA's requirement for change schedules and recommends against reliance on warning properties.⁽⁸⁾ In addition, NIOSH recently directed respirator manufacturers to change the cautionary language on cartridge and canister approval labels and user instructions to be consistent with 1910.134. Specifically, the statement "Do not wear for protection against organic vapors with poor warning properties or those which generate high heats of reaction with sorbent" must be changed to "Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs."⁽⁹⁾ The new cautionary language must appear on labels for all gas and vapor respirators sold after July 1, 2001. For more information, see the article entitled "New NIOSH Policies Support OSHA Respirator Standard" in this issue of *JobHealth Highlights*.

Misconception #4

Air-purifying respirators should not be used because diisocyanates are sensitizers or are "too hazardous." There is no doubt the effects of diisocyanate overexposure can be serious, particularly in individuals who become sensitized. However, this reasoning is contrary to accepted respirator decision logic. By definition, no respirator is required when exposure to an air contaminant is below the exposure limit. The purpose of a respirator is to reduce an exposure that is above an exposure limit to an

exposure that is *below* that limit. The diisocyanates have exposure limits. Any respirator that reduces a diisocyanate overexposure to a concentration below its exposure limit is acceptable. NIOSH changed its long-standing policy of recommending only the "most protective respirators" (e.g., SCBA) for use with carcinogens to reflect this logic.⁽¹⁰⁾ NIOSH now acknowledges that the entire range of respirators can be considered for protection against carcinogens with exposure limits. The same respirator decision logic is applicable to all air contaminants, including the diisocyanates.

Summary

Air-purifying respirators can be used safely and effectively to reduce exposures to the common diisocyanates. Appropriate cartridge change schedules can be developed to ensure cartridges are changed before breakthrough occurs. OSHA is correct in allowing employers to choose air-purifying respirators for diisocyanates if they are appropriate for their workplaces. As is the case with any other air contaminant, a complete respiratory protection program is necessary to ensure these respirators provide appropriate protection.

References

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(see *Diisocyanates* on page 4)

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Diisocyanates

(continued from page 2)

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New NIOSH policies support OSHA respirator standard

By Larry Janssen, C.I.H.

Introduction

The Occupational Safety and Health Administration (OSHA) revised its respiratory protection regulation, 29 CFR 1910.134, on January 8, 1998. Taken as a whole, the new standard represents a major step forward in the use of respirators. However, confusion was created because some provisions of the new regulation conflict with traditional respirator use practices.

Most of these traditional practices had one of three origins:

1. The previous version of 1910.134;
2. Limitations placed on respirators by their approvals;
3. Recommendations from "third party" organizations, including the American National Standards Institute (ANSI) and the National Institute for Occupational Safety and Health (NIOSH).

NIOSH's status is unique because it has regulatory authority for respirator approval, but can also make recommendations regarding respirator use. Because not everyone recognizes that NIOSH's function is largely advisory, some were especially concerned when the new OSHA standard conflicted with existing NIOSH recommendations. Fortunately, these discrepancies have been resolved by two NIOSH policy statements issued on August 4, 1999. The policies endorse essentially all the new provisions of 1910.134. They are available in their entirety at <http://www.3M.com/occsafety/html/fregulations.html>. This article will summarize the policies and briefly discuss their significance.

NIOSH policy on saccharin use

The first policy statement is entitled *Saccharin Use for Respirator Fit Testing* and describes NIOSH's new position on this topic.

In the past, NIOSH recommended against the use of saccharin because it was viewed as a potential occupational carcinogen. Previous NIOSH guidelines held that no exposure to any carcinogen was acceptable, regardless of how small the risk.

(see NIOSH policies on page 5)

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NIOSH policies

(continued from page 4)

In developing the new policy, NIOSH reviewed saccharin toxicity and calculated the potential risks associated with saccharin use for fit testing. Using very conservative assumptions, NIOSH estimated that saccharin exposure from fit testing would be 4,000 times lower than the “no adverse effect level” for carcinogenicity in rats. It was concluded that the risk to workers from a lifetime of fit tests would be very small, perhaps zero.

Therefore, NIOSH now recommends both saccharin and Bitrex® for qualitative fit testing. This is consistent with the revised OSHA respiratory protection standard. (For more information on saccharin, see the article in this issue of *JobHealth Highlights*.)

NIOSH policy on respirator use

The second policy statement is simply called *NIOSH Respirator*

Use Policy. It identifies five differences between previous NIOSH policies and the revised 1910.134. NIOSH’s resolution of each of these differences is summarized here.

1. Cartridge change schedules

Previous NIOSH policy allowed the use of chemical cartridges for gases and vapors only if:

- The contaminant had adequate warning properties (odor or irritation) which would alert the user that the cartridge was exhausted; or
- The cartridges had an end of service life indicator (ESLI) which would notify the wearer that it was time to change the cartridge.

This policy was consistent with the previous version of 1910.134 and respirator approval regulations. NIOSH 42 CFR Part 84 (formerly 30 CFR Part 11) includes the following limitation on the use of cartridges: “Not for use against

gases or vapors with poor warning properties (except where MSHA [sic Mine Safety and Health Administration] or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor) or those which generate high heats of reaction with sorbent material in the cartridge.”

The revised 1910.134 allows the use of ESLI, but does not permit reliance on warning properties. Instead, employers are required to determine how long cartridges will last and assure that they are changed before the end of their service lives. Because of this requirement, 1910.134 is the standard which “permit(s) such use for a specific gas or vapor.” Rather than identifying specific gases or vapors, OSHA allows the use of cartridges for all gaseous contaminants for which cartridge change schedules can be developed.

(see *NIOSH policies* on page 6)

Saccharin removed from carcinogen list

Since 1981, saccharin had been listed in the National Toxicology Program *Report on Carcinogens* with the designation “reasonably anticipated to be a human carcinogen.” It was removed or “delisted” from the 9th edition, which was released in May 2000.⁽¹⁾

The Calorie Control Council nominated saccharin for delisting, which led to an extensive review of the carcinogenicity data for saccharin. The review determined that cancer data from rodent studies did not meet the criteria required to list saccharin as a “reasonably anticipated human carcinogen.” It was determined that bladder tumors observed in rats arose from a mechanism that is not relevant to humans.

In addition, data from observation of people using saccharin over the past 20 years support the delisting.

The *Report on Carcinogens* (RoC) is published every two years. It identifies substances, mixtures or exposure circumstances that are “known” or “reasonably anticipated” to cause cancer, and to which a significant number of Americans are exposed. It is important to understand that the RoC identifies **potential** cancer hazards. A listing in the RoC does not necessarily mean a substance presents a cancer risk to an individual in daily life. The “known” designation indicates there is sufficient evidence of a cause and effect relationship between the exposure and human

cancer, based on studies in humans. A listing in the “reasonably anticipated” category means there is limited evidence of carcinogenicity in humans and/or sufficient evidence of carcinogenicity in experimental animals.

More information about the *Report on Carcinogens* is available at <http://ntp-server.niehs.nih.gov/NewHomeRoC/AboutRoC.html>.

Reference

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The NIOSH policy statement acknowledges that developing change schedules is a new exercise for many respirator users, and that some mistakes may be made. However, NIOSH reasons that there are fewer problems associated with change schedules than with reliance on warning properties because:

- There is a wide variation in individuals' ability to detect the odor of a given contaminant;
- An individual's ability to detect an odor may change due to:
 - Extended low exposures to contaminants;
 - Colds and other illnesses;
 - Distractions in the workplace competing for the individual's attention.

In other words, the use of change schedules represents a more reliable way to manage the use of cartridge respirators than reliance on warning properties.

Based on this logic, the new NIOSH policy recognizes the use of change schedules and recommends against reliance on warning properties. This is consistent with the revised 1910.134.

2. Irritant Smoke Fit Testing

The revised OSHA respiratory protection standard allows the use of irritant smoke for qualitative fit testing. Since 1993, NIOSH has recommended against the use of this method. This recommendation was made because hydrogen chloride (HCl) concentrations in excess of the exposure limit (EL) can be generated during required fit testing procedures. The EL is a ceiling limit (a concentration never to be exceeded) intended to prevent irritation. NIOSH has concluded that the fit test protocol

in the revised 1910.134 may overexpose test subjects to HCl either during the required sensitivity test or if the subject fails the fit test. **Therefore, contrary to 1910.134, NIOSH continues to recommend against the use of irritant smoke for fit testing.** (See NIOSH Health Hazard Evaluation Report HETA 93-040-2315 for additional information on HCl concentrations generated during irritant smoke fit testing.)

3. Saccharin Fit Testing

NIOSH restates its support for the use of saccharin for qualitative fit testing.

4. Voluntary Respirator Use

The new OSHA regulation allows a limited respiratory protection program (or no program at all for filtering facepieces) when respirator use is not required because of overexposure or employer policy, i.e., voluntary use. Prior to this revision, NIOSH recommended that a complete program be implemented whenever respirators were used, including situations in which respirators were worn voluntarily. NIOSH now believes that the burden of implementing a full program in the absence of overexposure discouraged employers from allowing voluntary respirator use. **The new NIOSH policy statement supports OSHA's voluntary use provisions.** Specifically, NIOSH believes that voluntary use will safely reduce worker exposures to concentrations well below established exposure limits. (See *JobHealth Highlights* Volume 17, Number 2 for further discussion of voluntary respirator use.)

5. Medical Evaluation Responsible Person

The revised OSHA standard allows medical evaluation of respirator users to be performed by a physician or other licensed health care professional (PLHCP). NIOSH is concerned that OSHA's definition of PLHCP does not limit non-physicians to those who are licensed for independent practice in **all** the health care services required by 1910.134. Therefore, NIOSH recommends that the only non-physicians responsible for medical evaluation (either conducting or supervising) should be nurse practitioners or physician assistants in those states where they are licensed for independent practice. **Thus, NIOSH is in partial disagreement with OSHA on this provision.**

Conclusion

NIOSH is to be commended for clearly stating its concurrence with nearly all the changes to 1910.134. It is encouraging that two important federal agencies are working together to bring respiratory protection program management into the 21st Century and to reflect today's technology. Continuation of past practice simply because "it's always been done this way" results in less effective protection for respirator users. Clearly, that is why OSHA revised its regulation.

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Documentation of the information relied upon, the basis for the change schedule, and the basis for relying on the information must be included in a written respirator program.

OSHA believes that chemical odor may not serve as a sufficient indicator for all workers to change chemical cartridges. Therefore, its revised respiratory protection standard, 29 CFR 1910.134, requires users of chemical cartridge respirators to implement a cartridge change schedule based on "objective information or data." In this way, used cartridges would be replaced before the chemical breaks through at a level that could result in worker overexposure.

3M Service Life Software is based on a model developed by G. Wood published in the American Industrial Hygiene Association Journal in January 1994. It calculates service life based on workplace conditions such as contaminant concentration, temperature, work rate, humidity and atmospheric pressure.

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