

Special Report

42 CFR Part 84: Respiratory Protective Devices Implications for Tuberculosis Protection

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This final rule was made available to the public at the Government Printing Office in Washington, DC, on June 2, 1995. It was published in the *Federal Register* on June 8, 1995, in Part II of that issue (60 FR 110:30336). This rule addresses the National Institute for Occupational Safety and Health (NIOSH) and Department of Labor/Mine Safety and Health Administration (MSHA) certification requirements for respiratory protective devices. Specifically, the rule replaces MSHA regulations at 30 CFR Part 11 with new public health regulations at 42 CFR Part 84, while also upgrading testing requirements for particulate filters. Concurrent with NIOSH publication of this new rule, MSHA published a final rule to remove existing regulations at 30 CFR Part 11, which are made obsolete by this final rule. NIOSH now will have exclusive authority for testing and certification of respirators with the exception of certain mine emergency devices, which will continue to be jointly certified by NIOSH and MSHA.

The certification of air-purifying respirators under the final rule will enable respirator users to select from a broader range of certified respirators. All of these new respirators will meet the performance criteria recommended by the Centers for Disease Control and Prevention (CDC) for respiratory devices used in healthcare settings for protection against *Mycobacterium tuberculosis*, the infectious agent that causes tuberculosis. The CDC published "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994," in the *Federal Register* (59 FR 54242) and *MMWR* (Vol. 43,

No. RR-13) on October 28, 1994. All nine classes of air-purifying particulate respirators to be certified under the provisions of the new particulate filter tests exceed the performance recommendations contained in the CDC guidelines. Several of these new classes of air-purifying, particulate respirators are expected to be less expensive than respirators with HEPA filters.

This action is the first of a series of modules that will upgrade current respirator approval standards incrementally. This modular approach will allow improvements to be implemented on a safety and health priority basis, as well as facilitate adaptation to new requirements by the manufacturers and users of respirators. It also will expedite the incorporation of technological advancements and will allow for expeditious response to emerging hazards.

Except for the particulate-filter standards, most of the existing regulations are incorporated into the new 42 CFR Part 84 without change. The revised testing standards for particulate filters will improve significantly the effectiveness of air-purifying filters in removing toxic particulates from the ambient air. These changes are consistent with two decades of advances in respiratory protection technology.

Under the new particulate filter tests, NIOSH will certify three classes of filters, N-, R-, and P-series, with three levels of filter efficiency, 95%, 99%, and 99.97%, in each class. All filter tests will employ the most penetrating aerosol size, 0.3 μm aerodynamic mass median diameter. The N-series will be tested against a mildly degrading aerosol of sodium chloride (NaCl). The R- and P-series filters will be tested

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95-SR-127. Rosenstock L. 42 CFR Part 84: Respiratory Protective Devices Implications for Tuberculosis Protection. *Infect Control Hosp Epidemiol* 1995;16:529-531.

TABLE 1

FILTER TESTS

Filter Designation	Minimum Efficiency	Test Agent	Maximum Test Challenge Loading
N100	99.97%	NaCl	200 mg filter loading
N99	99%	NaCl	200 mg filter loading
N95	95%	NaCl	200 mg filter loading
R100	99.97%	DOP	200 mg filter loading
R99	99%	DOP	200 mg filter loading
R95	95%	DOP	200 mg filter loading
P100	99.97%	DOP	200 mg filter loading
P99	99%	DOP	Maximum filter degradation
P95	95%	DOP	Maximum filter degradation

TABLE 2

SUMMARY OF THE EIGHT POINTS ON WHICH THE FINAL RULE DIFFERS FROM THE PROPOSAL

Proposal	Final Rule
Two categories of particulate filters (solid; solid and liquid).	Three categories of particulate filters (N-, R-, and P-series).
Filter efficiency tests applied to all air-purifying particulate filters.	Filter efficiency tests apply only to air-purifying particulate filters for nonpowered respirators. Filters for powered air-purifying respirators will be addressed in another module.
Inhalation resistance maximum at 30 mm; exhalation resistance maximum at 20 mm.	Inhalation resistance maximum at 35 mm; exhalation resistance maximum at 25 mm.
Isoamyl acetate tightness test for particulate respirators was included.	Isoamyl acetate tightness test was eliminated from the certification procedures.
Certification of filters was based on statistical evaluation of results from 30 filters tested.	Pass/fail test based on results from 20 filters tested. All must pass.
Pending Part 11 applications would be processed for 6 months, and no new Part 11 applications would be accepted after the effective date of Part 84.	All pending Part 11 applications will be processed. All new applications received after the effective date of Part 84 will be considered applications for approval under Part 84.
Approval holders allowed to manufacture and sell Part 11 filters as approved devices for 2 years from the effective date of Part 84.	Approval holders allowed to manufacture and sell Part 11 filters as approved devices for 3 years from the effective date of Part 84.
No provisions were included for the continued issuance of extensions of existing 30 CFR part 11 approvals.	A new Subpart KK has been added for the issuance of extensions of existing 30 CFR Part 11 approvals to address respirator nonconformances when there is a demonstrated safety or health need during the 3-year transition period, and for the approval of powered air-purifying respirators until addressed in a later module.

against a highly degrading aerosol of dioctylphthalate (DOP) (Table 1).

Tested to a specified maximum loading level (200 mg), the N- and R-series will be certified with the recognition that in some settings time-use limitations will apply. A single shift time limitation, for example, may be appropriate. In addition to possible time-use restrictions, the N-series filters should be restricted to use in those workplaces free of oil or other severely degrading aerosols. The R-series filters would not have similar aerosol-use restrictions. The P-series filters will be tested with DOP until no further decrease in filter efficiency is observed. The P-series filters have neither aerosol-use nor time-use limitations. As for any filter, service time will be limited by considerations of hygiene and increased breathing resistance due to filter loading.

The final rule differs from the proposal (59 FR 26850) in eight ways. These changes are summarized in Table 2. This final rule was effective on July 10, 1995.

For further information contact Richard W. Metzler, Chief, Certification and Quality Assurance Branch, Division of Safety Research, NIOSH, 1095 Willowdale Rd, Morgantown, WV 26505-2888; telephone (304) 285-5907. Copies of this final rule may be downloaded from the NIOSH World Wide Web page (<http://www.cdc.gov/niosh/homepage.html>) or may be obtained by calling the NIOSH toll-free information number, (800) 35-NIOSH, option 5, 9:00 AM to 4:00 PM, ET). Arrangements also have been made for this final rule to be listed on the electronic bulletin boards of the Government Printing Office, (202) 512-1387, and the Department of Labor, (202) 219-4784.

Hepatitis B Linked to Cryopreservation Tank

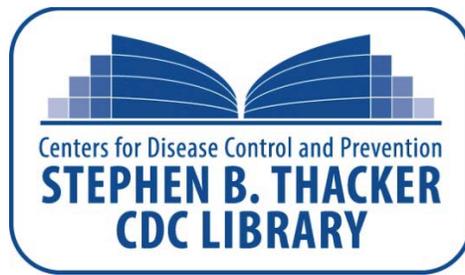
by **Gina Pugliese, RN, MS**
Medical News Editor

A contaminated cryopreservation tank has been identified as the source of infection of a cluster of six cases of acute hepatitis B that occurred at the University College Hospital in London, England. The six patients, whose stays in the hospital did not overlap, all had hematologic

or other malignant disorders and had bone marrow or stem cells stored in a single cryopreservation tank for future autologous transplantation. Human DNA, HBsAg, and HBV DNA with sequences identical to those from four patients with related infections subsequently were found in the liquid nitrogen. Leakage of the cryopreservation bags used to store bone marrow harvested from the first

patient during acute HBV infection led to contamination of the tank and its contents with HBV and subsequent transmission to patients after transplantation.

FROM: Tedder RS, Zuckerman MA, Goldstone AH, et al. Hepatitis B transmission from contaminated cryopreservation tank. *Lancet* 1995; 346:137-140.



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