

the proposed rule, this terminology has been substituted because it more accurately reflects the purpose of the medical examination. None of the public commenters objected to this change.

ANSI Z88.6-1984 also provides guidelines for the scope of an examination which would demonstrate that a worker was medically fit to use respiratory protection devices. The guidelines include consideration of pulmonary function, cardiovascular factors, neurological and psychological conditions, among others. The NRC staff believes that these guidelines provide an acceptable working definition of the term "medically fit."

It should be noted that the NRC staff position is that a complete physical examination of each respirator user is not required, only an initial medical examination and annual or periodic review of medical status and that physicians need not administer each test personally, but may designate individuals such as office nurses as long as the physician is responsible for the program. It is also important to note that Occupational Safety and Health Administration (OSHA), State and other requirements regarding use of respirators and fitness evaluation for exposure to other toxic materials are not waived by this rulemaking.

#### Agreement States

The amendment applies to all NRC licensees. Agreement States must establish and maintain compatible regulations and programs. Most radiation protection provisions in 10 CFR part 20 are classified as Division I matters of compatibility. However, this rulemaking defines minimum procedures needed to ensure health and safety. As such, an Agreement State should have the flexibility to keep the 12-month frequency or to impose an alternate frequency of examinations if considerations in their State warrant such an approach. The rule is therefore a Division II matter of compatibility. This rulemaking was discussed with representatives of Agreement States at the Organization of Agreement State Managers Workshop and Public Meeting on Rulemaking in Herndon, VA, on July 12, 1994. No comments or objections were offered by the States. Although Agreement States had the opportunity to comment on this proposed change during the public comment period, none submitted comments.

#### Description

The provisions of 10 CFR 20.1703 (a)(3)(v) are changed to require determination by a physician prior to

initial fitting of respirators, and periodically thereafter, either every 12 months or at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment. Frequency of reexamination is changed from "at least every 12 months," to "either every 12 months thereafter or periodically at a frequency determined by a physician," and the term "medically fit" is substituted for the current term "physically able," to make clearer the purpose of the medical determination.

#### Impact

The Commission believes that this change constitutes a reduction of regulatory burden and an increase in flexibility for licensees, without any significant reduction in worker health or safety. The medical profession contributed significantly to development of the reduced frequencies recommended by ANSI and it is therefore expected that physicians performing examinations will be guided by the ANSI recommendations. ANSI recommended a frequency of reexamination based on age: every 5 years up to age 35; every 2 years up to age 45; and annually thereafter. A change in procedures or license conditions will be needed to implement a change in frequency of reexamination.

The respiratory use medical examination is estimated to cost approximately \$150 per examination. The number of examinations performed during an outage at a nuclear power plant is estimated to be 500. If 60 plants have outages each year, the current cost for annual medical examinations is at least \$4,500,000. An examination of the demographics of the nuclear workforce ( $\frac{1}{2}$  <35 years;  $\frac{1}{3}$  >35 but <45;  $\frac{1}{6}$  >45) suggests that the number of medical examinations could easily be halved thus saving \$2.25 million each year just during maintenance or refueling outages at nuclear power plants. Clearly, considerable savings will be realized by this change freeing resources for more effective health and safety efforts.

Certain materials licensees such as fuel cycle facilities, some research facilities including broad scope academic licensees, and some manufacturing groups also have respiratory protection programs. The impacts on these licensees are minimal because the number of respirator users is small. The rule is expected to result in a reduction in costs due to a reduced frequency of medical reexamination for these licensees.

Although some costs will be incurred by licensees in making revisions to procedures and license conditions,

these costs will be offset by the increased flexibility and savings resulting from reduced reexamination frequency.

Ten letters of public comment were received on the proposed rule: The Nuclear Energy Institute (NEI) and seven nuclear utilities including Tennessee Valley Authority (TVA), the University of Texas System, and the National Institute for Occupational Safety and Health (NIOSH) of the Department of Health and Human Services (HHS).

NEI, the seven nuclear utilities, and the University of Texas System all supported the proposed rule. These commenters agreed that the proposed changes would constitute a reduction of regulatory burden and an increase in flexibility for licensees and Agreement States, without any significant reduction in worker health and safety. Several agreed that the recommended age-related frequencies for reexamination found in ANSI Z88.6-1984 should not be codified and should continue to provide useful guidance to physicians and other professionals in determining the suitability of individuals for respirator use. The proposed rule was characterized as appropriately performance-based and as not restricting the exercise of professional medical judgment.

Several commenters agreed that the initial determination by a physician should occur prior to initial fitting of respirators, rather than prior to first field use. These commenters observed that although this change would provide further reduction in burden, there is no clear evidence that such a change would not adversely impact the current level of protection of public health and safety. Others agreed that considerable liability would result if a worker were to experience an adverse reaction to a respirator during an initial fit-test without having had the requisite medical determination.

NIOSH supported the NRC goal of reducing the time and effort in the medical fitness determination process. They suggested however, that the NRC should use the word "evaluation" rather than "examination" when discussing the determination of medical fitness. NIOSH said that the content of an evaluation could include, medical history, questionnaire, physical examination, laboratory tests (such as dextrocardiogram, spirometry, or exercise testing) and results of a monitored worker trial period.

NIOSH recommended that a medical fitness evaluation be performed initially, and annually thereafter or after any significant illness, injury or surgery