We will not acknowledge receipt of FAX transmittals. We will treat facsimile comments as originals.

By E-Mail: You may submit comments of any length by electronic mail to nprm@atfhq.atf.treas.gov. Electronic mail comments must include:
- A reference to Notice No. 946;
- Your e-mail address; and
- Your name and post office address.

We will not acknowledge receipt of e-mail comments. We will treat e-mail comments as originals.

By On-Line Form: You may also submit comments electronically using the comment form provided with the online copy of Notice No. 946 on the ATF Internet web site at http://www.atf.treas.gov/alcohol/rules/index.htm. We will treat comments submitted via the web site as originals.

Can I Review Comments Received?
You may view copies of the comments on Notice No. 946 by appointment at the ATF Reference Library, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC 20226, telephone (202) 927–7890. You may request copies of the comments (at 20 cents per page) by writing to the ATF Reference Librarian at the address shown above.

For the convenience of the public, ATF will post comments received in response to Notice No. 946 on the ATF web site. All comments posted on our web site will show the name of the commenter, but will have street addresses, telephone numbers, and e-mail addresses removed. We may also omit voluminous attachments or material that we do not consider suitable for posting. In all cases, the full comment will be available in the ATF library as noted above. To access online copies of the comments on this rulemaking, visit http://www.atf.treas.gov/, select “Regulations,” and then “Notices of proposed rulemaking (Alcohol).” Then click on the “View Comments” button for Notice No. 946.

Drafting Information
The principal author of Notice No. 946 is William H. Foster, and the author of this notice is Michael D. Hoover, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 7
Advertising, Authority delegations, Beer, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Authority and Issuance
This notice is issued under the authority contained in 27 U.S.C. 205.

Thomas R. Crone,
Chief, Regulations Division.

I. Submission of Comments on This Notice and Internet Access to Comments and Submissions
You may submit comments in response to this notice by (1) hard copy, or (2) FAX transmission (facsimile), or (3) electronically through the OSHA Webpage. Please note that you cannot attach materials, such as studies or journal articles, to electronic comments. If you have additional materials, you must submit three copies of the materials to the OSHA Docket Office at the address above. The additional materials must clearly identify your electronic comments by name, date, subject and docket number so we can attach them to your comments. Because of security-related problems there may be a significant delay in the receipt of comments by regular mail. Contact the

DEPARTMENT OF LABOR
Occupational Safety and Health Administration
29 CFR Part 1910
[Docket No. H–0054a]
RIN 1218–AB45
Occupational Exposure to Hexavalent Chromium (CrVI)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for information.

SUMMARY: OSHA requests data, comments, and information on issues relevant to occupational exposure to hexavalent chromium (CrVI), including: Significant epidemiological, animal, and in vitro studies; the relationship between occupational exposures to CrVI and the development of adverse health effects; industry profiles of use, current exposures, and population at risk; types and availability of control methodologies; analytical methods; medical screening and surveillance procedures; exposure assessment programs; employee training programs; and use of personal protective equipment.

DATES: Comments must be submitted by the following dates:
Hard Copy: Your comments must be submitted (postmarked or sent) by November 20, 2002. Facsimile and electronic transmission: Your comments must be sent by November 20, 2002. (Please see the SUPPLEMENTARY INFORMATION provided below for additional information on submitting comments.)

ADDRESSES: Regular mail, express delivery, hand-delivery, and messenger service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. H–0054a, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC, 20210; telephone (202) 693–2350. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Facsimile: If your comments, including any attachments, are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648. You must include the docket number of this notice, Docket No. H–0054a, in your comments.

Electronic: You may submit comments but not attachments through the Internet at http://ecommnts.osha.gov. (See the SUPPLEMENTARY INFORMATION provided below for additional information on submitting comments.)
OSHA Docket Office at (202)-693–2350 for information about security procedures concerning the delivery of materials by express delivery, hand delivery and messenger service.

All comments and submissions will be available for inspection and copying at the OSHA Docket Office at the above address. Comment and submissions posted on OSHA’s Web site are available at http://www.osha.gov. OSHA cautions you about submitting personal information such as social security numbers and birth dates. Contact the OSHA Docket Office at (202)–693–2350 for information about materials not available through the OSHA Webpage and for assistance in using the Webpage to locate docket submissions.

II. Background

Properties and Uses. Chromium exists in several oxidation states. Its most important natural source is as the mineral chromite (FeO•Cr2O3). Common forms of chromium compounds are trivalent chromium (CrIII), and hexavalent chromium (CrVI). CrVI can be produced when CrIII is heated in the presence of mineral bases and oxygen. Such a change (from CrIII to CrVI) also occurs as a by-product of welding or cutting operations on stainless steel. In addition, a portion of CrIII used in refractory bricks can convert to CrVI during normal furnace operations.

CrVI compounds are characterized by high melting points, very high boiling points, varying solubilities, a wide array of colors, corrosion resistance and resistance to acid. These properties make chromium ideal for use in such widely diversified products as corrosion-resistant materials, pigments, coatings, metal plating, and chemicals.

Health risks associated with occupational exposure to CrVI. Epidemiologic studies of workers exposed to CrVI have consistently shown a positive correlation between exposure to CrVI and excess lung cancer. See, e.g., Machle and Gregorius (1948, Ex. 7–2); U.S. Public Health Service/Gafner (1953, Ex. 7–3); Baetjer (1950, Ex. 7–6; Hayes et al (1979, Ex. 7–15); Braver (1985, Ex. 7–17); Mancuso (1975, Ex. 18–3; 1997 Exs. 23, 24); and Gibb et al (2000, Ex. 25). The International Agency for Research on Cancer (IARC) (Ex. 18–1) and the U.S. Environmental Protection Agency (EPA) (Ex. 19–1) have classified CrVI as a human carcinogen based on excess lung cancers found in workers involved in chromate production, chromate pigment production, and chromium plating. The American Conference for Governmental Hygienists (ACGIH) classifies water-insoluble and water-soluble Cr IV compounds, zinc chromate, and strontium chromate as class A1 (confirmed human) carcinogens. (2002, ACGIH, TLVs® and BEIs®, Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices).

Occupational exposure to CrVI has also been associated with non-cancer health effects of the skin, such as dermatoses and chrome holes; and problems of the respiratory system including nasal septum irritation and perforation.

Occupational health regulation of CrVI exposure. In 1971, OSHA adopted and made applicable to general industry a national consensus standard (ANSI Z37.7–1971) for chronic acid and chromate compounds (compounds that contain chromium in its hexavalent state), 29 U.S.C. 655(a). The general industry standard sets a permissible exposure limit ("PEL") for hexavalent chromium compounds at 100 micrograms per cubic meter (µg/m3) as a ceiling concentration measured as chromic acid (CrO3), 29 CFR 1910.1000, Table Z–1 and Z–2. In 1971, OSHA also adopted, as its hexavalent chromium standard for construction work, an established federal standard that had been promulgated under the Construction Safety Act, 40 U.S.C. 333. That standard sets a PEL of 100 µg/m³ (measured as CrO3) as an 8-hour time-weighted average (8-hour TWA) for chromic acid and chromates, 29 CFR.1926.55.

In 1993, the Oil, Chemical and Atomic Workers Union (OCAW) and Public Citizen Health Research Group petitioned OSHA to issue an Emergency Temporary Standard (ETS) to immediately lower the PEL in all workplaces to 0.5 µg/m³, measured as an 8-hour TWA. OSHA denied the petition because it failed to satisfy the stringent criteria for an ETS. However, OSHA opened a rulemaking docket and began to collect information that would be relevant to a CrVI rule.

The information available to date indicates that occupational exposures to CrVI presents a number of complex and difficult issues (e.g., data gaps on current usage of and exposure to CrVI, differences in opinion on the interpretation of health effects data). In this notice, OSHA is seeking data, comments, and information on a variety of topics relevant to the agency’s review of occupational exposure to CrVI. The topics include: Adverse health effects associated with occupational exposure to CrVI; methods, costs, and effectiveness of control strategies that can reduce exposure to CrVI; and medical management of exposed employees.

The questions below highlight the areas of concern to OSHA. When answering specific numbered questions below, please key your responses to the number of the question, explain the reasons supporting your views, and identify and provide relevant information on which you rely, including, but not limited to, data, studies and articles. The public is also welcome to comment on other issues raised by this notice.

A. Health Effects

As discussed above, OSHA is aware of a number of studies reporting an association between adverse health effects and exposure to CrVI. In this notice, OSHA is seeking information associated with, and analysis of, the most recent and important studies that the agency can use to evaluate health effects.

(1) What studies (including positive and negative studies) should OSHA consider useful in assessing the potential carcinogenic, mutagenic, and non-carcinogenic health risks of CrVI exposure? Explain your scientific rationale for recommending these studies including potential strengths and weaknesses such as size of the population (or sample) studied, characterization of exposure, and confounding factors.

(2) Are there any recent studies that examine the dermal effects of CrVI exposure?

(3) Are there any studies showing adverse health effects resulting from routes of occupational CrVI exposure other than dermal contact and inhalation? What are those adverse health effects?

(4) Are there any important studies related to the dose response behavior of CrVI, including cellular, mechanistic, and dosimetric considerations? For instance, are any health effects of CrVI dependent on the time period over which exposure occurs rather than dependent on the total cumulative dose received or are there data that suggest CrVI exhibits a threshold effect?

(5) Do short-term peak exposures play a role in causing adverse CrVI health effects?
effects? If so, what studies are available that examine these types of effects. How should short-term peak exposures be addressed when evaluating CrVI health effects data? In answering, please consider both animal and human studies.

(6) How should OSHA address animal and epidemiological studies that rely on different analytical methods than are currently available to assess exposure when evaluating the health effects data contained in those studies?

(7) Animal studies are designed to test individual CrVI compounds (e.g., lead chromate, strontium chromate, potassium chromate). Epidemiological studies are designed to evaluate CrVI exposures in individual workplaces or by types of industries (e.g., chromate production, welding, pigment manufacture). Can or should the results from these individually tested compounds or work settings/industries be grouped together to assess the overall toxicity of CrVI or should each compound or industry be analyzed separately? Do different CrVI compounds have specific properties (e.g., solubility) that should be taken into consideration when evaluating animal or human studies?

B. Risk Assessment

OSHA is aware of the following risk assessments on human studies of lung cancer among workers exposed to CrVI via inhalation: The 1984 risk assessment prepared by the U.S. EPA (Ex. 19–1); the 1986 risk assessment prepared by Gibb et al. (Ex. 7–102); and the 1995 risk assessment prepared by K.S. Crump Division (Ex. 13–5). These risk assessments relied heavily on the epidemiologic studies conducted by Mancuso (1975, Ex. 18–3) and Hayes et al. (Ex. 1979, Ex. 7–15). Since these risk assessments, Gibb et al. (2000, Ex. 25) has updated the investigation of the cohort originally studied by Hayes et al. (Ex. 7–15). This study notes limitations in the Mancuso data. OSHA is seeking the best available data to use in assessments of occupational risks of CrVI-related adverse health effects to CrVI-exposed workers. OSHA is especially interested in studies of occupational exposure that quantify exposure data and control for important confounding variables, have good statistical power, and are well conducted.

(8) Do the EPA (Ex. 19–1), the Gibb et al (Ex. 7–102) and the K.S. Crump (Ex. 13–5) risk assessments adequately characterize the lung cancer risks of CrVI? Please provide your rationale including information on studies selected and risk assessment methodology.

(9) What approaches (i.e., methods, models, data used) should OSHA use for estimating risk of CrVI exposure?

(10) Are there biological endpoints, besides lung cancer, that could or should be used to estimate the occupational risk to CrVI-exposed workers?

(11) What mathematical models are appropriate to quantify the risk of cancer or other adverse health effects associated with exposure to CrVI? What are the strengths and weaknesses of those models?

(12) Animal studies can add value to a risk assessment in areas such as dose-response. What, if any, animal studies are appropriate for use in a CrVI risk assessment? Which animal species, tumor incidences, route(s) of administration, and dose level(s) would be most appropriate.

(13) When extrapolating from animal studies, what additional corrections, if any, should be made to account for the route of exposure used in the study (e.g., topical application, injection, inhalation)?

(14) What other factors should OSHA take into consideration when analyzing risks associated with exposure to CrVI at the current permissible exposure level and in determining safe levels of exposure to CrVI?

C. Methods of Analyzing Exposure Levels

In June 1998, OSHA revised and validated its analytical method “ID—215” to evaluate airborne occupational exposures of CrVI (Ex. 29). The method, ID—215, is very sensitive, with a qualitative detection limit of 0.001 ug/m² for a 960 liter air sample. The quantitative detection limit is 0.003 ug/m² for a 960 liter air sample.

Method ID—215 is an improvement over prior analytical methods for airborne CrVI. Prior methods may have been subject to greater interference from other heavy metals. In addition, reducing agents such as Fe(II) could convert CrVI to CrIII and thus reduce the amount of CrVI reported as measured.

(15) Are there methods other than ID—215 for measuring exposure levels in the range of 0.02 to 10 ug/m³ that would be as accurate as, or more accurate than, OSHA’s ID—215?

(16) Are there methods for conducting wipe samples?

(17) Are there methods for conducting field-tests?

(18) Are there methods to determine the presence or absence of CrVI in buildings for which no blueprints are in existence?

D. OSHA’s Investigations into Occupational Exposures, Control Measures, and Technological and Economic Feasibility

In 1994, OSHA contractor Meridian Research, Inc. delivered to the agency a report, Selected Chapters of an Economic Impact Analysis for a Revised OSHA Standard for Chromium VI: Introduction, Industry Profiles, Exposure Profiles, Technological Feasibility (for 6 Industries) and Environmental Impacts. (Ex. 26). This report was based, in part, on earlier analyses conducted by Centaur (Ex. 27).

The purpose of the Meridian report was to “evaluate the impact a revision of the Occupational Safety and Health Administration (OSHA) standard for CrVI may have in the principal industries that would be affected by the new standard” and to “[identify] the potentially affected industries, [discuss] the structure of these industries, [determine] the size of the population at risk, [identify] current levels of exposure, and [describe] some of the economic impacts potentially associated with a reduction in CrVI exposures.”

Meridian identified many industries with potential CrVI exposure for which Meridian was unable to provide full information. For example, OSHA lacks information on number of employees exposed, number of sites, nature and level of exposures, controls and how CrVI is used in processes for industries such as woodworking, refractory brick production, portland cement uses and leather tanning. Moreover, in the years since the Meridian report, market forces, technological changes and environmental factors have, in varying degrees, altered the magnitude, frequency, and duration of employee exposures in the industries that have traditionally handled CrVI. Because of these trends, some industries have abandoned or dramatically reduced usage of CrVI.

For these reasons, OSHA has worked to obtain additional information on affected industries and workers by utilizing the following sources: (1) Inspection reports collected and summarized within OSHA’s computerized Integrated Management Information System; (2) occupational health studies; and (3) data related to site visits conducted by the National Institute for Occupational Safety and Health (NIOSH) under an inter-agency agreement between NIOSH and OSHA. OSHA sought information on patterns of employee exposure, specific routes of exposure, type and cost of engineering controls in particular industries, and types and costs of personal protective equipment.
equipment. OSHA has worked closely with NIOSH on this update. NIOSH has completed its field surveillance program and has delivered reports on roughly one-half of the sites. It has also summarized exposure data for the remaining sites. (Ex. 28). OSHA requests that the public review the industrial and process conditions and worker activities changes to such an extent that the profiles would need revision? Are there industries or processes with CrVI exposures that are not covered in these reports? (20) Are the exposure profiles reported by Meridian and NIOSH reasonably representative of affected industry processes or have there been changes in the statistical distribution of worker exposures in those profiles? OSHA requests exposure data that will enable the Agency to expand its current data to estimate CrVI exposures? Describe any other programs you have implemented for assessing an employee’s initial exposure to CrVI. (27) Describe any follow-up or subsequent exposure assessments that you conduct. How often do you conduct any such follow-up or subsequent exposure assessments?

Control Measures and Technological Feasibility

(28) Have there been technological changes within your industry that have influenced the magnitude, frequency, or duration of exposure to CrVI and the means by which employers attempt to control exposures? The Agency requests that commenters describe in detail any technological changes within industries that have altered medical links between control technologies and data on exposure levels associated with the application of controls.

(29) Have you installed engineering controls or adopted work practices with the purpose of reducing exposure to CrVI? If so, have these controls or work practices resulted in a reduction of CrVI exposure? Please give specific examples where the introduction of controls and work practices have reduced exposure to CrVI.

(30) Has there been a trend to eliminate CrVI from production processes, products and services? If so, OSHA requests that interested parties comment on the success of substitution efforts. In particular, OSHA requests that commenters estimate the percentage reduction in CrVI, and the extent to which CrVI is still necessary in their processes within product lines or production activities. OSHA also requests that commenters describe any economic, social or other barriers to substitution.

Economic Impact

(31) The Agency seeks comment on potential impacts of reducing occupational exposures to CrVI, in terms of costs of controls, reduction in illness, cost savings related to reduced occupational exposure to CrVI? Why are they necessary and how are these respirators selected? Identify the type, model number, and manufacturer of such respirators by task.

(34) What other types of protective equipment, such as gloves, aprons, or other clothing, are provided to employees? How is this protective equipment selected? Under what conditions (e.g., exposure level, type of operations, duration of exposure) are protective equipment and respirators used? Are there processes or areas where its infeasible to use respirators or other protective equipment to protect against exposure to CrVI? Describe those situations and explain why it is difficult to use protective equipment. How are employees protected in those situations?

F. Employee Training

(37) What job categories are included in your training program for reducing risks associated with CrVI exposure? How do you determine which job categories receive training?

(38) Describe the training employees receive, including the length and frequency of the training course, the topics covered, the availability of training aids such as audio-visual aids and written operating instructions. Also
describe any other factors that affect the cost of training and provide any estimate of the cost of training.

(39) How do you determine the effectiveness of the training? Are decreased absenteeism, decreased medical/insurance costs, decreased accident rates/severity, and increased productivity factors in your determination? Are there any other factors in your determination? How are language barriers to training addressed?

(40) Are there ways in which CrVI-related training could be improved?

G. Medical Programs

OSHA is interested in medical programs that employers use or could use in the identification of signs and symptoms of illnesses associated with occupational exposures to CrVI. OSHA is especially interested in those programs focusing on prevention or treatment of CrVI-related injuries or illnesses for employees who have occupational exposure to CrVI.

(41) What medical or clinical examinations have potential usefulness in identifying workers with adverse health effects resulting from occupational CrVI exposure? Include specific tests or procedures used in any such examination and other useful information, such as the types of laboratories used for biological tests, the frequency of examinations and follow-up tests, and the contents of the examinations?

(42) What CrVI-related illnesses or conditions have you observed? What programs do you have in place to detect and refer employees for medical management?

(43) Do you have any information to suggest that the use of an employee medical management program designed to prevent adverse CrVI-related health effects such as “chrome holes” (ulcerations of the skin caused by CrVI) or nasal septum perforations reduces the incidence or prevalence of other CrVI-related effects, such as lung or other cancers?

(44) Are there any studies that suggest that elevated biological indicators (such as CrVI in blood or urine) are associated with an elevated risk of lung cancer or other adverse health effects such as asthma? What are normal levels of chromium in blood or urine in non-occupational exposed populations? Are these indicators affected by diet?

(45) Is there any information that suggests that biological indicators other than CrVI in blood or urine could be appropriate for evaluating risk of adverse health effects associated with CrVI exposures among workers?

(46) Are there any studies that suggest that chromium with other valences, other than in the CrVI valence, can be taken up by the red blood cells?

(47) When you evaluate an employee’s chromium-blood levels, do you use whole blood or packed red blood cells? What is the significance of using one over the other?

(48) How do you determine eligibility in your medical screening program?

(49) Provide any information relating reduction in adverse health outcomes to the implementation of medical surveillance programs.

(50) Are your healthcare costs less after medical screening is initiated?

(51) Do you ever remove employees because of illness or injury related to CrVI exposure? If so, describe the circumstances of the removal and potential return. For how long are these employees removed? Are workers ever permanently removed?

(52) Please describe any special medical screening and treatment you conduct for chrome holes, dermatoses, and nasal septal perforations.

H. Environmental Effects

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), the Council on Environmental Quality (CEQ) regulations (49 CFR, Part 1500, 43 F.R. 55978, November 29, 1978), and the Department of Labor (DOL) NEPA Compliance Regulations (29 CFR, Part 11); [45 F.R. 51187 et seq., August 1, 1980] require that OSHA give appropriate consideration to environmental issues and impacts of proposed actions significantly affecting the quality of the human environment. OSHA is currently collecting written information and data on possible environmental impacts that could occur outside of the workplace (e.g., exposure to the community through contaminated air/water, contaminated waste sites, etc.) if the agency were to issue guidance or revise the existing standard for occupational exposure to CrVI. Such information should include both negative and positive environmental effects that could be expected to result from guidance or a revised standard. Specifically, OSHA requests comments and information on the following:

(53) How might reducing occupational exposures to CrVI exposure affect the environment?

(54) What is the potential direct or indirect impact of reducing employee exposure to CrVI exposure on water and air pollution, energy usage, solid waste disposal, etc.?

(55) How would any available CrVI substitutes alter ambient air quality, water quality, solid waste disposal, and land use?

(56) Are there situations in which reducing CrVI exposures to employees would be inconsistent with meeting environmental regulations?

I. Impact on Small Business Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), OSHA is required to assess the impact of proposed and final rules on small entities. OSHA requests that members of the small business community, or other parties familiar with regulation of small business, address any special circumstances facing small firms in controlling occupational exposure to CrVI.

(57) How many and what kinds of small businesses or other small entities in your industry could be affected by reducing exposures to CrVI? Describe any such effects.

(58) Are there special issues that make control of CrVI exposures more difficult or more costly in small firms?

(59) Are there any reasons that the benefits of reducing occupational exposure to CrVI might be less in small firms than in larger firms? With regard to potential impacts on small firms, please describe specific concerns that should be addressed. Please describe alternatives that might serve to minimize these impacts while meeting the requirements of the OSH Act.

J. Duplication/Overlapping/Conflicting Rules

(60) Are there any federal regulations that might duplicate, overlap or conflict with guidance or a revised standard concerning CrVI? If so, identify which ones and explain how they would duplicate, overlap or conflict.

(61) Are there any federal programs in areas such as defense or energy that might be impacted by guidance or a revised standard concerning CrVI? If so, identify which ones and explain how they would be impacted.

Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary’s Order 3–2000, and 29 CFR Part 1911.
Evaluation of Certain Respiratory Conditions

Since revised evaluation criteria for respiratory conditions were established in 1996, the evaluation of most respiratory conditions has been based primarily on the results of specific pulmonary function tests (PFT’s). Conditions evaluated on that basis include chronic bronchitis (diagnostic code 6600), pulmonary emphysema (diagnostic code 6603), chronic obstructive pulmonary disease (diagnostic code 6604), interstitial lung disease (diagnostic codes 6825–6833), and restrictive lung disease (diagnostic codes 6840–6845). In some cases, the rating schedule provides alternative evaluation criteria that may be used instead of PFT’s. These include measures of the maximum exercise capacity; the presence of pulmonary hypertension (documented by echocardiogram or cardiac catheterization), cor pulmonale, or right ventricular hypertrophy; episode(s) of respiratory failure; and a requirement for outpatient oxygen therapy.

Alternative criteria were established in order to provide more than one route to reach a particular level of evaluation and, at the same time, avoid requiring that veterans undergo additional invasive, risky, costly, or time-consuming tests when one or more objective and reliable tests or findings suitable for evaluation purposes are already of record.

Applying the PFT results can be difficult in some cases. We therefore propose to add provisions that would clarify the use of PFT’s in evaluating respiratory conditions to 38 CFR 4.96 as paragraph (d), titled “Special provisions for the application of evaluation criteria for diagnostic codes 6600, 6603, 6604, 6825–6833, and 6840–6845.” We developed these provisions after consultation with the Pulmonary/Critical Care Advisory Committee of the Veterans Health Administration.

Chronic bronchitis (diagnostic code 6600) is an example of a respiratory condition that is evaluated primarily on the basis of PFT’s but also has alternative evaluation criteria. The criteria for a 100-percent evaluation are FEV1 of 1 (Forced Expiratory Volume in one second) less than 40 percent of predicted value, the ratio of FEV1 to FVC (Forced Vital Capacity) less than 40 percent, DLCO (SB) (Diffusion Capacity of the Lung for Carbon Monoxide by the Single Breath Method) less than 40 percent predicted, maximum exercise capacity less than 13 ml/kg/min oxygen consumption (with cardiac or respiratory limitation), cor pulmonale (right heart failure), right ventricular hypertrophy, pulmonary hypertension (shown by echocardiogram or cardiac catheterization), episode(s) of acute respiratory failure, or a requirement for outpatient oxygen therapy. The criteria for a 60-percent evaluation are FEV1 of 40- to 55-percent predicted, FEV1/FVC of 40 to 55 percent, DLCO (SB) of 40- to 55-percent predicted, or maximum oxygen consumption of 15 to 20 ml/kg/min (with cardiorespiratory limit). The criteria for a 30-percent evaluation are FEV1 of 56- to 70-percent predicted, FEV1/FVC of 56 to 70 percent, or DLCO (SB) 56- to 65-percent predicted. The criteria for a 10-percent evaluation are FEV1 of 71- to 80-percent predicted, FEV1/FVC of 71 to 80 percent, or DLCO (SB) 66- to 80-percent predicted.

For the first provision, we propose to state when pulmonary function testing is not needed for disability evaluation purposes. The first instance would be when there is a maximum exercise capacity of record that is 20 ml/kg/min or less (which would result in a 60- or 100-percent evaluation). Although this test is not routinely done, and not all facilities have the necessary equipment to conduct the test, if available, it is a reliable and precise way to assess respiratory disability, so it may be used to evaluate when it is available and is reported at levels that would warrant a 60- or 100-percent evaluation. If not of record, however, evaluation will be based on alternative criteria. The second instance would be when pulmonary hypertension (documented by an echocardiogram or cardiac catheterization), cor pulmonale, or right ventricular hypertrophy has been diagnosed. Any of these would result in a 100-percent evaluation. The third instance would be when there is a history of one or more episodes of acute respiratory failure, and the fourth instance would be when there is a requirement for outpatient oxygen therapy, because either of these also establishes entitlement to a 100-percent evaluation.

Routine pulmonary function testing may or may not include a measurement of DLCO (SB) (Diffusion Capacity of the Lung for Carbon Monoxide by the Single Breath Method). The DLCO (SB) is not useful or valid in assessing every respiratory condition (for example, it is not valid in cases where the lung volume is decreased), so it is up to the examiner to assess whether it would provide useful information in a particular case. We therefore propose to add a second provision that would state that if the DLCO (SB) is not of record, evaluation will be based on alternative