

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****[Docket No. DEA-392]****Bulk Manufacturer of Controlled Substances Application: Apertus Pharmaceuticals****ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before May 26, 2015.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on March 20, 2014, Apertus Pharmaceuticals, 331 Consort Drive, St. Louis, Missouri 63011, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance               | Schedule |
|------------------------------------|----------|
| Marihuana (7360) .....             | I        |
| Tetrahydrocannabinols (7370) ..... | I        |

The company plans to divide the synthesized cannabidiol, with a portion going for sale as an API in nabiximol. The raw material will be used to synthesize dronabinol. Therefore, they anticipate consuming and purchasing small quantities of CS for generating data to support the Drug Master File

with the FDA including validation batches, standards and stability studies.

No other activity for this drug code is authorized for this registration.

Dated: March 20, 2015.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator.*

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**BILLING CODE 4410-09-P**

**DEPARTMENT OF LABOR****Occupational Safety and Health Administration****[Docket No. OSHA-2012-0035]****Traylor/Skanska/Jay Dee Joint Venture: Grant of a Permanent Variance**

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

**ACTION:** Notice.

**SUMMARY:** In this notice, OSHA grants a permanent variance to Traylor/Skanska/Jay Dee Joint Venture from the provisions of OSHA standards that regulate work in compressed air environments at 29 CFR 1926.803.

**DATES:** The permanent variance specified by this notice becomes effective on March 27, 2015 and shall remain in effect until January 31, 2016.

**FOR FURTHER INFORMATION CONTACT:** Information regarding this notice is available from the following sources:

*Press inquiries:* Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N-3647, Washington, DC 20210; telephone: (202) 693-1999; email: [Meilinger.frank2@dol.gov](mailto:Meilinger.frank2@dol.gov).

*General and technical information:* Contact Mr. Kevin Robinson, Acting Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N-3655, Washington, DC 20210; phone: (202) 693-2110 or email: [robinson.kevin@dol.gov](mailto:robinson.kevin@dol.gov).

**SUPPLEMENTARY INFORMATION:**

*Copies of this Federal Register notice.* Electronic copies of this **Federal Register** notice are available at <http://www.regulations.gov>. This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's Web page at <http://www.osha.gov>.

**I. Notice of Application**

On April 26, 2012, Traylor Bros., Inc., 835 N. Congress Ave., Evansville, IN 47715, and Traylor/Skanska/Jay Dee Joint Venture, Blue Plains Tunnel, 5000 Overlook Avenue SW., Washington, DC 20032, submitted under Section 6(d) of the Occupational Safety and Health Act of 1970 ("OSH Act"; 29 U.S.C. 655) and 29 CFR 1905.11 ("Variances and other relief under section 6(d)") an application for a permanent variance from several provisions of the OSHA standard that regulates work in compressed air at 29 CFR 1926.803. OSHA is addressing this request as two separate applications: (1) Traylor Bros., Inc. ("Traylor") request for a permanent variance for future tunneling projects; and (2) Traylor/Skanska/Jay Dee Joint Venture, Blue Plains Tunnel ("Traylor JV" or "the applicant"). This notice only addresses the Traylor JV application for an interim order and permanent variance for the Blue Plains Tunnel project.<sup>1</sup> This notice does not address the Traylor application for a permanent variance for future projects. That request will be addressed separately.

Traylor JV also requested an interim order pending OSHA's decision on the application for a variance (Ex. OSHA-2012-0035-0008). Specifically, this notice addresses the application submitted by Traylor JV for the Blue Plains Tunnel project in which the applicant seeks a permanent variance and interim order from the provisions of the standard that: (1) Prohibit compressed-air worker exposure to pressures exceeding 50 pounds per square inch (p.s.i.) except in an emergency (29 CFR 1926.803(e)(5));<sup>2</sup> (2) require the use of the decompression values specified in decompression tables in Appendix A of the compressed-air standard for construction (29 CFR 1926.803(f)(1)); and (3) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and .803(g)(1)(xvii), respectively).

The applicant is a contractor that works on complex tunnel projects using recently developed equipment and procedures for soft-ground tunneling. The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation

<sup>1</sup> See Section III discussion of condition A Scope.

<sup>2</sup> The decompression tables in Appendix A of subpart S express the maximum working pressures as pounds per square inch gauge (p.s.i.g.), with a maximum working pressure of 50 p.s.i.g. Therefore, throughout this notice, OSHA expresses the 50 p.s.i. value specified by § 1926.803(e)(5) as 50 p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

techniques in conjunction with an earth pressure balanced tunnel boring machine (EPBTBM).

According to its application, Traylor is currently the managing partner of Traylor/Skanska/Jay Dee Joint Venture ("Traylor JV"), the general contractor for the DC Water and Sewer Authority's project to construct the Blue Plains Tunnel. Traylor JV asserts that generally, it bores tunnels (*i.e.*, Blue Plains Tunnel) below the water table through soft soils consisting of clay, silt, and sand. Traylor JV employs specially trained personnel for the construction of the tunnel, and states that this construction will use shielded mechanical-excavation techniques. Traylor JV asserts that its workers perform hyperbaric interventions at pressures greater than 50 p.s.i.g. in the excavation chamber of the EPBTBM; these interventions consist of conducting inspections and maintenance work on the cutter-head structure and cutting tools of the EPBTBM.

Traylor JV asserts that innovations in tunnel excavation, specifically with EPBTBMs, have, in most cases, eliminated the need to pressurize the entire tunnel. This technology negates the requirement that all members of a tunnel-excavation crew work in compressed air while excavating the tunnel. These advances in technology modified substantially the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803. Such advances reduce the number of workers exposed, and the total duration of exposure, to hyperbaric pressure during tunnel construction.

Using shielded mechanical-excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, EPBTBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies, and isolate that pressure to the forward section (the working chamber) of the EPBTBM. Interventions in the working chamber (the pressurized portion of the EPBTBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention. Interventions occur to inspect or maintain the mechanical-excavation components located in the working chamber. Maintenance conducted in the working chamber includes changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head.

In addition to innovations in tunnel-excavation methods, Traylor JV asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. According to Traylor JV, the use of decompression protocols incorporating oxygen is at least as effective for tunnel workers as compliance with the decompression tables specified by the existing OSHA standard (29 CFR part 1926, subpart S, Appendix A decompression tables). These hyperbaric exposures are possible due to advances in technology, a better understanding of hyperbaric medicine, and the development of a project-specific Hyperbaric Operations Manual (HOM) that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers.

OSHA initiated a technical review of the Traylor JV's variance application and developed a set of follow-up questions that it sent to Traylor JV on September 17, 2012 (Ex. OSHA-2012-0035-0003). On October 26, 2012, Traylor JV submitted its response and a request for an interim order for the Blue Plains Tunnel Project (Ex. OSHA-2012-0035-0008). In its response to OSHA's follow-up questions, Traylor JV indicated that the maximum pressure to which it is likely to expose workers during interventions for the Blue Plains Tunnel project is 52 p.s.i.g. and does not involve the use of trimix breathing gas (composed of a mixture of oxygen, nitrogen, and helium in varying concentrations used for breathing by compressed air workers for compression and decompression when working at pressures exceeding 73 p.s.i.g.). Therefore, to work effectively on this project, Traylor JV must perform hyperbaric interventions in compressed air at pressures higher than the maximum pressure specified by the existing OSHA standard, 29 CFR 1926.803(e)(5), which states: "No employee shall be subjected to pressure exceeding 50 p.s.i.g. except in emergency" (see footnote 2).

OSHA considered Traylor JV's application for a permanent variance and interim order for the Blue Plains Tunnel project. OSHA determined that Traylor JV proposed an alternative that will provide a workplace as safe and healthful as that provided by the standard. On July 11, 2013, OSHA granted Traylor JV a project-specific interim order for the completion of the Blue Plains Tunnel (Ex. OSHA-2012-0035-0011) in order to permit the applicant to begin work while OSHA continued to consider its application for

a permanent variance. Further, on December 11, 2014, OSHA published a **Federal Register** notice announcing Traylor JV's application for a permanent variance and interim order, grant of an interim order, and request for comments (79 FR 73631) for the Blue Plains Tunnel project.

## II. The Variance Application

### A. Background

As indicated earlier in this notice, Traylor JV asserts that the advances in tunnel excavation technology described in Section I of this notice modified significantly the equipment and methods used by contractors to construct subaqueous tunnels, thereby making several provisions of OSHA's compressed-air standard for construction at 29 CFR 1926.803 inappropriate for this type of work. These advances reduce both the number of workers exposed, and the total duration of exposure, to the hyperbaric conditions associated with tunnel construction.

Using shielded mechanical-excavation techniques, in conjunction with pre-cast concrete tunnel liners and backfill grout, EPBTBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face, through various geologies, while isolating that pressure to the forward section (working or excavation chamber) of the EPBTBM.

Interventions involving the working chamber (the pressurized chamber at the head of the EPBTBM) take place only after the applicant halts tunnel excavation and prepares the machine and crew for an intervention. Interventions occur to inspect or maintain the mechanical-excavation components located in the forward portion of the working chamber. Maintenance conducted in the forward portion of the working chamber includes changing replaceable cutting tools, disposable wear bars, and, in rare cases, repairs to the cutter head due to structural damage.

In addition to innovations in tunnel-excavation methods, research conducted after OSHA published its compressed-air standard for construction in 1971, resulted in advances in hyperbaric medicine. In this regard, the applicant asserts that the use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the existing OSHA standard (29 CFR part 1926, subpart S, Appendix A decompression tables). According to the applicant, contractors routinely and safely expose employees performing

interventions in the working chamber of EPBTBMs to hyperbaric pressures up to 75 p.s.i.g., which is 50% higher than maximum pressure specified by the existing OSHA standard (see 29 CFR 1926.803(e)(5)).

The applicant contends that the alternative safety measures included in its application provide its workers with a place of employment that is at least as safe and healthful as they would obtain under the existing provisions of OSHA's compressed-air standard for construction. The applicant certifies that it provided employee representatives of affected workers with a copy of the variance application.<sup>3</sup> The applicant also certifies that it notified its workers of the variance application by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant informed its workers and their representatives of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

*B. Variance From Paragraph (e)(5) of 29 CFR 1926.803, Prohibition of Exposure to Pressure Greater Than 50 p.s.i.g. (See Footnote 1)*

The applicant states that it may perform hyperbaric interventions at pressures greater than 50 p.s.i.g. in the working chamber of the EPBTBM; this pressure exceeds the pressure limit of 50 p.s.i.g. specified for nonemergency purposes by 29 CFR 1926.803(e)(5). The EPBTBM has twin man locks, with each man lock having two compartments. This configuration allows workers to access the man locks for compression and decompression, and medical personnel to access the man locks if required in an emergency.

EPBTBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of propel cylinders, a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. As noted earlier, the forward-most portion of the EPBTBM is the working chamber, and this chamber is the only pressurized segment of the EPBTBM. Within the shield, the working chamber consists of two sections: The staging chamber and the forward working chamber. The staging chamber is the section of the

working chamber between the man-lock door and the entry door to the forward working chamber. The forward working chamber is immediately behind the cutter head and tunnel face.

The applicant will pressurize the working chamber to the level required to maintain a stable tunnel face. Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the working chamber. The applicant asserts that most of the hyperbaric interventions will be around 14.7 p.s.i.g. However, the applicant maintains that they may have to perform interventions at pressures up to 52 p.s.i.g.

During interventions, workers enter the working chamber through one of the twin man locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The maximum crew size allowed in the forward working chamber is three. At certain hyperbaric pressures (*i.e.*, when decompression times are greater than work times), the twin man locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man lock at its disposal.

The applicant developed a project-specific HOM for the Blue Plains Tunnel (Ex. OSHA-2012-0035-0007) that describes in detail the hyperbaric procedures and required medical examinations used during the tunnel-construction project. The HOM discusses standard operating procedures and emergency and contingency procedures. The procedures include using experienced and knowledgeable man-lock attendants who have the training and experience necessary to recognize and treat decompression illnesses and injuries. The attendants are under the direct supervision of the hyperbaric supervisor and attending physician. In addition, procedures include medical screening and review of prospective compressed-air workers (CAWs). The purpose of this screening procedure is to vet prospective CAWs with medical conditions (*e.g.*, deep vein thrombosis, poor vascular circulation, and muscle cramping) that could be aggravated by sitting in a cramped space (*e.g.*, a man lock) for extended periods or by exposure to elevated pressures and compressed gas mixtures. A transportable recompression chamber (shuttle) is available to extract workers from the hyperbaric working chamber

for emergency evacuation and medical treatment; the shuttle attaches to the topside medical lock, which is a large recompression chamber. The applicant believes that the procedures included in the HOM provide safe work conditions when interventions are necessary, including interventions above 50 p.s.i.g.

*C. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables*

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR part 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules that supplement breathing air used during decompression with pure oxygen. The applicant asserts that these decompression protocols are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR part 1926, subpart S.

Accordingly, the applicant proposes to use the 1992 French Decompression Tables to decompress CAWs after they exit the hyperbaric conditions in the working chamber. Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. Traylor JV asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of elimination of nitrogen; (4) improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by about 33 percent as compared to air decompression; and (6) reducing inflammation. As described in Section V of this notice, OSHA's review of the use of oxygen in several major tunneling projects completed in the past indicates that it contributed significantly to the reduction of decompression illness (DCI) and other associated adverse effects observed and reported among CAWs.

In addition, the HOM requires a physician certified in hyperbaric medicine to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant also will be present during

<sup>3</sup> See the definition of "Affected employee or worker" in section VI. D.

hyperbaric exposures and decompression. This man-lock attendant will operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor (competent person), trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions, and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

The applicant asserts that at higher hyperbaric pressures, decompression times exceed 75 minutes. The HOM establishes protocols and procedures that provide the basis for alternate means of protection for CAWs under these conditions. Accordingly, based on these protocols and procedures, the applicant requests to use the 1992 French Decompression Tables for hyperbaric interventions up to 52 p.s.i.g. for completion of the Blue Plains Tunnel project. The applicant is committed to follow the decompression procedures described in the Blue Plains Tunnel project-specific HOM during these interventions.

*D. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression*

According to the applicant, breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions, and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in DCI, commonly referred to as "the bends." This description of the etiology of DCI is consistent with current scientific theory and research on the issue (see footnote 13 in this notice discussing a 1985 NIOSH report on DCI).

The 1992 French Decompression Tables proposed for use by the applicant provide for stops during worker decompression (*i.e.*, staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of

DCI than the OSHA decompression requirements of 29 CFR 1926.803, which specify the use of automatically regulated continuous decompression (see footnotes 9 through 14 in this notice for references to these studies).<sup>4</sup> In addition, the applicant asserts that staged decompression is at least as effective as an automatic controller in regulating the decompression process because:

1. A hyperbaric supervisor (a competent person experienced and trained in hyperbaric operations, procedures, and safety) directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops; and

2. The use of the 1992 French Decompression Tables for staged decompression offers an equal or better level of management and control over the decompression process than an automatic controller and results in lower occurrences of DCI.

Accordingly, the applicant is applying for a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conduct the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

*E. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber*

The OSHA compressed-air standard for construction requires employers to

<sup>4</sup> In the study cited in footnote 11, starting at page 338, Dr. Eric Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, "Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 psig . . . to the surface took 1 h, at least half the time is spent at pressures less than 2 psig . . . , which provides less and less meaningful bubble suppression . . ." In addition, the report referenced in footnote 5 under the section titled, "Background on the Need for Interim Decompression Tables" addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that "[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control."

use a special decompression chamber when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Another provision of OSHA's compressed-air standard calls for locating the special decompression chamber adjacent to the man lock on the atmospheric pressure side of the tunnel bulkhead (see 29 CFR 1926.803(g)(2)(vii)). However, since only the working chamber of the EPBTBM is under pressure, and only a few workers out of the entire crew are exposed to hyperbaric pressure, the man locks (which, as noted earlier, connect directly to the working chamber) are of sufficient size to accommodate the exposed workers. In addition, available space in the EPBTBM does not allow for an additional special decompression lock. Again, the applicant uses the man locks, each of which adequately accommodates a three-member crew, for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man lock during decompression stops or exit the man lock and move into the staging chamber where additional space is available. This alternative enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

*F. Previous Tunnel Construction Variance*

OSHA notes that on May 23, 2014, it granted a sub-aqueous tunnel construction permanent variance to Tully/OHL USA Joint Venture (79 FR 29809) from the same provisions of the standard that regulates work in compressed air (at 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application. Generally, the alternate conditions in this notice are based on and very similar to the alternate conditions of the previous permanent variance.

*G. Multi-State Variance*

As stated earlier in this notice, Traylor JV applied for an interim order for its Blue Plains Tunnel project only. On July 11, 2013, OSHA granted an interim order to cover only the Blue Plains Tunnel project, which is located entirely in the District of Columbia and thus under Federal OSHA's exclusive jurisdiction. Further, on December 11, 2014, OSHA published a **Federal Register** notice announcing Traylor JV's application for a permanent variance and interim order, grant of an interim order, and request for comments (79 FR 73631).

Additionally, twenty-seven state safety and health plans have been approved by OSHA under section 18 of the (OSH) Act.<sup>5</sup> As part of the permanent variance process, the Directorate of Cooperative and State Programs will notify the State Plans of Traylor JV's variance application and grant of the Blue Plains permanent variance. In considering Traylor JV's application for a permanent variance and interim order, OSHA noted that four states have previously granted sub-aqueous tunnel construction variances and imposed different or additional requirements and conditions (California, Nevada, Oregon, and Washington). California also promulgated a new standard<sup>6</sup> for similar sub-aqueous tunnel construction work.

### III. Description of the Conditions Specified for the Permanent Variance

This section describes the alternative means of compliance with 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) and provides additional detail regarding the conditions that form the basis of Traylor JV's permanent variance.

#### *Condition A: Scope*

The scope of the permanent variance limits coverage to the work situations specified under this condition. Clearly defining the scope of the permanent variance provides Traylor JV, Traylor JV's employees, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the permanent variance applies.

According to 29 CFR 1905.11, an employer or class or group of employers<sup>7</sup> may request a permanent variance for a specific workplace or workplaces. If granted, the variance applies to the specific employer(s) that submitted the application. In this instance, the permanent variance applies to the applicant, Traylor/Skanska/Jay Dee Joint Venture at the

Blue Plains Tunnel project and does not apply to any other employers.

#### *Condition B: Application*

This condition specifies the circumstances under which the permanent variance is in effect, notably only for hyperbaric work performed during interventions. The condition places clear limits on the circumstances under which the applicant can expose its employees to hyperbaric pressure.

#### *Condition C: List of Abbreviations*

Condition C defines a number of abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the permanent variance.

#### *Condition D: Definitions*

The condition defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. Defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the permanent variance.

#### *Condition E: Safety and Health Practices*

This condition requires the applicant to develop and submit to OSHA an HOM specific to the Blue Plains project at least six months before using the EPBTBM for tunneling operations. Additionally, the condition includes a series of related hazard prevention and control requirements and methods (e.g., decompression tables, job hazard analyses (JHA), operations and inspections checklists, incident investigation, recording and notification to OSHA of recordable hyperbaric injuries and illnesses, etc.) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Review of the HOM enables OSHA to: (1) Determine that the safety and health instructions and measures it specifies are appropriate and do adequately protect the safety and health of the CAWs; and (2) request the applicant to revise or modify the HOM if it finds that the hyperbaric safety and health procedures are not suitable for the specific project and do not adequately protect the safety and health of the CAWs. Once approved, the project-specific HOM becomes part of the variance, thus enabling OSHA to

enforce its safety and health procedures and measures.<sup>8</sup>

#### *Condition F: Communication*

Condition F requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication ensures that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during EPBTBM operations.

#### *Condition G: Worker Qualification and Training*

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work ensures that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition also requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if they believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

<sup>5</sup> Five State Plans (Connecticut, Illinois, New Jersey, New York, and the Virgin Islands) limit their occupational safety and health authority to state and local employers only. State Plans that exercise their occupational safety and health authority over both public- and private-sector employers are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming.

<sup>6</sup> See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at <http://www.dir.ca.gov/title8/sb7g26a154.html>.

<sup>7</sup> A class or group of employers (such as members of a trade alliance or association) may apply jointly for a variance provided an authorized representative for each employer signs the application and the application identifies each employer's affected facilities.

<sup>8</sup> Grant of the July 11, 2013, project-specific interim order constituted OSHA's approval of Traylor JV's Blue Plains Tunnel project-specific HOM.

*Condition H: Inspections, Tests, and Accident Prevention*

Condition H requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the EPBTBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the EPBTBM, and maintain these documents at the job site for the duration of the job. This requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

*Condition I: Compression and Decompression*

This condition requires the applicant to consult with its designated medical advisor regarding special compression or decompression procedures appropriate for any un-acclimated CAW. This provision ensures that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during EPBTBM operations. Accordingly, CAWs requiring acclimation have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the EPBTBM.

*Condition J: Recordkeeping*

Condition J requires the applicant to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under this provision, in concert with the information provided under condition K (using the OSHA 301 Incident Report form to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7,

1904.8 through 1904.12), enables the applicant and OSHA to determine the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.<sup>9</sup>

*Condition K: Notifications*

Under this condition, the applicant is required, within specified periods to: (1) Notify OSHA of any recordable injuries, illnesses, in-patient hospitalizations, amputations, loss of an eye, or fatalities that occur as a result of hyperbaric exposures during EPBTBM operations; (2) provide OSHA with a copy of the incident investigation report (using OSHA 301 form) of these events; (3) include on the 301 form information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide its certification that it informed affected workers of the incident and the results of the incident investigation; (5) notify the Office of Technical Programs and Coordination Activities (OTPCA) and the Baltimore/Washington DC Area Office within 15 working days should the applicant need to revise its HOM to accommodate changes in its compressed-air operations that affect its ability to comply with the conditions of the permanent variance; and (6) provide OTPCA and the Baltimore/Washington DC Area Office, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

These notification requirements enable the applicant, its employees, and OSHA to determine the effectiveness of the permanent variance in providing the requisite level of safety to the applicant's workers and, based on this determination, whether to revise or revoke the conditions of the permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

This condition also requires the applicant to notify OSHA if it ceases to

do business, has a new address or location for its main office, or transfers the operations covered by the permanent variance to a successor company. In addition, the condition specifies that OSHA must approve the transfer of the permanent variance to a successor company. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the permanent variance, and expedite the Agency's administration and enforcement of the permanent variance. Stipulating that an applicant must have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by the permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the permanent variance.

**IV. Comments on the Proposed Variance Application**

OSHA received no comments on the proposed variance, including no comments from State Plans.

**V. Decision**

After reviewing Traylor JV's proposed variance as described above, and having received no comment, OSHA determines that:

A. Traylor JV developed, and proposed to implement, effective alternative measures to the prohibition of using compressed air under hyperbaric conditions exceeding 50 p.s.i.g. The alternative measures include use of engineering and administrative controls of the hazards associated with work performed in compressed-air conditions exceeding 50 p.s.i.g. while engaged in the construction of a subaqueous tunnel using advanced shielded mechanical-excavation techniques in conjunction with an EPBTBM. Prior to conducting interventions in the EPBTBM's pressurized working chamber, the applicant halts tunnel excavation and prepares the machine and crew to conduct the interventions. Interventions involve inspection, maintenance, or repair of the mechanical-excavation components located in the working chamber.

B. Traylor JV developed, and proposed to implement, safe hyperbaric work procedures, emergency and contingency procedures, and medical examinations for the Blue Plains Tunneling project's CAWs. The applicant compiled these standard operating procedures into a project-specific HOM (Ex. OSHA-2012-0035-0007). The HOM discusses the

<sup>9</sup> See 29 CFR part 1904 Recording and Reporting Occupational Injuries and Illnesses ([http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=9631](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631)); recordkeeping forms and instructions (<http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf>); OSHA Recordkeeping Handbook (<http://www.osha.gov/recordkeeping/handbook/index.html>); and updates to OSHA's recordkeeping rule and Web page ((79 FR 56130); <http://www.osha.gov/recordkeeping2014/index.html>)).

procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use. Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.*, staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor (competent person), trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

C. Traylor JV developed, and proposed to implement, a training program to instruct affected workers in the hazards associated with conducting hyperbaric operations.

D. Traylor JV developed, and proposed to implement, an effective alternative to the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine, to oversee all hyperbaric operations.

E. Traylor JV developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by the standard. EPBTBM technology permits the tunnel's work areas to be at atmospheric pressure, with only the face of the EPBTBM (*i.e.*, the working chamber) at elevated pressure during interventions. The applicant limits interventions conducted in the working chamber to performing required inspection, maintenance, and repair of the cutting tools on the face of the

EPBTBM. The EPBTBM's man lock and working chamber provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times up to 360 minutes. Therefore, OSHA preliminarily determined that the EPBTBM's man lock and working chamber function as effectively as the special decompression chamber required by the standard.

OSHA conducted a review of the scientific literature regarding decompression to determine whether the alternative decompression method (*i.e.*, the 1992 French Decompression Tables) Traylor JV proposed provide a workplace as safe and healthful as that provided by the standard. Based on this review, OSHA determined that tunneling operations performed with these tables<sup>10</sup> resulted in a lower occurrence of DCI than the decompression tables specified by the standard.<sup>11 12 13</sup>

The review conducted by OSHA found several research studies supporting the determination that the 1992 French Decompression Tables resulted in a lower rate of DCI than the decompression tables specified by the standard. For example, H. L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging

from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996);<sup>14</sup> this project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events, and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08%. The DCI incidence in the study by H. L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A. OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.<sup>15</sup> Therefore, OSHA concludes that use of the 1992 French Decompression Tables protects workers at least as effectively as the OSHA decompression tables.

Based on a review of available evidence, the experience of State Plans that either granted variances (Nevada, Oregon and Washington)<sup>16</sup> or promulgated a new standard (California)<sup>17</sup> for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's variance application, OSHA is granting the permanent variance.

Under section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), the Agency finds that when the employer complies with the conditions of the following order, the working conditions of the employer's workers are at least as safe and healthful as if the employer complied with the working conditions specified by paragraphs (e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, Traylor JV will: (1) Comply with the conditions listed in section VI of this notice for the period between the grant of the interim order and completion of the Blue Plains Tunnel project, but no later than January 31, 2016; (2) comply fully with

<sup>10</sup>In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) Staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

<sup>11</sup>Kindwall, EP (1997). Compressed air tunneling and caisson work decompression procedures: Development, problems, and solutions. *Undersea and Hyperbaric Medicine*, 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard.

<sup>12</sup>Sealey, JL (1969). Safe exit from the hyperbaric environment: Medical experience with pressurized tunnel operations. *Journal of Occupational Medicine*, 11(5), pp. 273–275. This article reported 210 treated cases of DCI among 38,600 hyperbaric exposures between 13 and 34 p.s.i.g. over a 32-month period, for an incidence of 0.54% for the decompression tables specified by the Washington State safety standards for compressed-air work, which are similar to the tables in the OSHA standard. Moreover, the article reported 51 treated cases of DCI for 3,000 exposures between 30 and 34 p.s.i.g., for an incidence of 1.7% for the Washington State tables.

<sup>13</sup>In 1985, the National Institute for Occupational Safety and Health (NIOSH) published a report entitled "Criteria for Interim Decompression Tables for Caisson and Tunnel Workers"; this report reviewed studies of DCI and other hyperbaric-related injuries resulting from use of OSHA's tables. This report is available on NIOSH's Web site: <http://www.cdc.gov/niosh/topics/decompression/default.html>.

<sup>14</sup>Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine*, 29(3), pp. 172–188.

<sup>15</sup>Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS*, pp. 1–5 (see Ex. OSHA–2012–0035–0008).

<sup>16</sup>These state variances are available in the docket: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

<sup>17</sup>See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at <http://www.dir.ca.gov/title8/sb7g26a154.html>.

all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of its application for a permanent variance. Additionally, this final order will remain in effect until OSHA modifies or revokes it in accordance with 29 CFR 1905.13.

## VI. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the employer on July 11, 2013, and affirmed on December 11, 2014 (79 FR 73631). OSHA issues this final order authorizing Traylor/Skanska/Jay Dee Joint Venture ("Traylor JV") to comply with following conditions instead of complying with the requirements of paragraphs 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii). This final order applies to all employees of Traylor JV exposed to hyperbaric conditions at the Blue Plains Tunnel project. These conditions are:

### A. Scope

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the Blue Plains Tunnel project, a tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of an EPBTBM;
2. Performed under compressed-air and hyperbaric conditions up to 52 p.s.i.g;
3. In the EPBTBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber;
4. Except for the requirements specified by 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii), Traylor JV must comply fully with all other applicable provisions of 29 CFR part 1926; and
5. This order remains in effect until one of the following conditions occurs: (1) Completion of the Blue Plains Tunnel project, but no later than January 31, 2016; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

### B. Application

The permanent variance applies only when Traylor JV stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform interventions (*i.e.*, inspect, maintain, or repair the mechanical-excavation components), or

exit the working chamber after performing interventions.

### C. List of Abbreviations

Abbreviations used throughout this permanent variance include the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. EPBTBM—Earth Pressure Balanced Tunnel Boring Machine
5. HOM—Hyperbaric Operations and Safety Manual
6. JHA—Job hazard analysis
7. OSHA—Occupational Safety and Health Administration
8. OTPCA—Office of Technical Programs and Coordination Activities

### D. Definitions

The following definitions apply to this permanent variance. These definitions supplement the definitions in Traylor JV's project-specific HOM.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term "employee" has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

2. *Atmospheric pressure*—the pressure of air at sea-level, generally 14.7 p.s.i.a., 1 atmosphere absolute, or 0 p.s.i.g.

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures up to 52 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.<sup>18</sup>

5. *Decompression illness* (also called decompression sickness or the bends)—an illness caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include (but are not limited to): Joint pain (also known as the "bends" for agonizing pain or the "niggles" for slight pain); areas of bone destruction (termed dysbaric osteonecrosis); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder

dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).<sup>19</sup>

**Note:** Health effects associated with hyperbaric intervention but not considered symptoms of DCI can include: Barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and is caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O<sub>2</sub>) at elevated partial pressures).

6. *Earth Pressure Balanced Tunnel Boring Machine*—the machinery used to excavate the tunnel.

7. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.<sup>20</sup>

8. *Hyperbaric*—at a higher pressure than atmospheric pressure.

9. *Hyperbaric intervention*—a term that describes the process of stopping the EPBTBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutter head structure.

10. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by Traylor JV for working in compressed air during the Blue Plains' tunnel project.

11. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

12. *Man lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into or out of a working chamber.

13. *Pressure*—a force acting on a unit area. Usually expressed as pounds per square inch (p.s.i.).

14. *p.s.i.*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.

15. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i. Adding 14.7 to a pressure

<sup>19</sup> See Appendix 10 of "A Guide to the Work in Compressed Air Regulations 1996," published by the United Kingdom Health and Safety Executive available from NIOSH at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf>.

<sup>20</sup> Also see 29 CFR 1910.146(b).

<sup>18</sup> Adapted from 29 CFR 1926.32(f).

expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

16. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure; pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g.

17. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.<sup>21</sup>

18. *Working chamber*—an enclosed space in the EPBTBM in which CAWs perform interventions, and which is accessible only through a man lock.

#### E. Safety and Health Practices

1. Traylor JV must develop and implement an HOM specific to the Blue Plains project, and submit the HOM to OSHA at least six months before using the EPBTBM. Traylor JV must receive a written acknowledgement from OSHA regarding the acceptability of the HOM.<sup>22</sup> The HOM shall provide the governing safety and health requirements regarding hyperbaric exposures during the tunnel-construction project.

2. Traylor JV must implement the safety and health instructions included in the manufacturer's operations manuals for the EPBTBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

3. Traylor JV must use air as the only breathing gas in the working chamber.

4. Traylor JV must use the 1992 French Decompression Tables for air, air-oxygen, and oxygen decompression specified in the HOM, specifically the extracted portions of the 1992 French Decompression tables titled "French Regulation Air Standard Tables."

5. Traylor JV must equip man-locks used by its employees with an oxygen-delivery system as specified by the HOM. Traylor JV must not store oxygen or other compressed gases used in conjunction with hyperbaric work in the tunnel.

6. Workers performing hot work under hyperbaric conditions must use

flame-retardant personal protective equipment and clothing.

7. In hyperbaric work areas, Traylor JV must maintain an adequate fire-suppression system approved for hyperbaric work areas.

8. Traylor JV must develop and implement one or more JHAs for work in the hyperbaric work areas, and review, periodically and as necessary (e.g., after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk assessment<sup>23</sup> indicates are essential to prevent injury or illness.

9. Traylor JV must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by this permanent variance (including all procedures required by the HOM, which this variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

10. Traylor JV must ensure that the safety and health provisions of the HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations.<sup>24</sup>

#### F. Communication

1. Prior to beginning a shift, Traylor JV must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rock slides, cave-ins, flooding, fires, or explosions.

2. Traylor JV must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) Traylor JV must use an independent power supply for powered communication systems, and these systems must operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) Traylor JV must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

<sup>23</sup> See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

<sup>24</sup> See ANSI/ASSE A10.33–2011, American National Standard for Construction and Demolition Operations—Safety and Health Program Requirements for Multi-Employer Projects, for reference.

#### G. Worker Qualifications and Training

Traylor JV must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, in hyperbaric conditions, and document this instruction. The instruction must include topics such as:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (e.g., barotrauma, nitrogen narcosis, and oxygen toxicity).

(d) How to avoid discomfort during compression and decompression; and

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure.

3. Repeat the instruction specified in paragraph (2) of this condition periodically and as necessary (e.g., after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers make this training available to OSHA personnel and notify the OSHA at OSHA's national office and OSHA's Baltimore/Washington DC Area Office before the training takes place.

#### H. Inspections, Tests, and Accident Prevention

1. Traylor JV must initiate and maintain a program of frequent and regular inspections of the EPBTBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2) by:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks and weekly inspections of the EPBTBM.

2. If the competent person determines that the equipment constitutes a safety hazard, Traylor JV must remove the

<sup>21</sup> Adapted from 29 CFR 1926.32(m).

<sup>22</sup> See footnote 8.

equipment from service until it corrects the hazardous condition and has the correction approved by a qualified person.

3. Traylor JV must maintain records of all tests and inspections of the EPBTBM, as well as associated corrective actions and repairs, at the job site for the duration of the job.

#### *I. Compression and Decompression*

Traylor JV must consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

#### *J. Recordkeeping*

Traylor JV must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904 Recording and Reporting Occupational Injuries and Illnesses), resulting from exposure of an employee to hyperbaric conditions by completing the OSHA 301 Incident Report form and OSHA 300 Log of Work Related Injuries and Illnesses.

**Note:** Examples of important information to include on the OSHA 301 Incident Report form (along with the corresponding question on the form) are: The task performed (Question (Q) 14); an estimate of the CAW's workload (Q 14); the composition of the gas mixture (e.g., air or oxygen (Q 14)); the maximum working pressure (Q 14); temperature in the work and decompression environments (Q 14); unusual occurrences, if any, during the task or decompression (Q 14); time of symptom onset (Q 15); duration between decompression and onset of symptoms (Q 15); type and duration of symptoms (Q 16); a medical summary of the illness or injury (Q 16); duration of the hyperbaric intervention (Q 17); possible contributing factors (Q 17); the number of prior interventions completed by the injured or ill CAW (Q 17); the number of prior interventions completed by the injured or ill CAW at this working pressure (Q 17); contact information for the treating healthcare provider (Q 17); and date and time of last hyperbaric exposure for this CAW.

In addition to completing the OSHA 301 Incident Report form and OSHA 300 Log of Work Related Injuries and Illnesses, Traylor JV must maintain records of:

1. The date, times (e.g., began compression, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

3. The total number of interventions and the amount of hyperbaric work time at each pressure.

4. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

#### *K. Notifications*

1. To assist OSHA in administering the conditions specified herein, Traylor JV must:

(a) Notify the OTPCA and the Baltimore/Washington DC Area Office of any recordable injuries, illnesses, in-patient hospitalizations, amputations, loss of an eye, or fatality (by submitting the completed OSHA 301 Incident Report form <sup>25</sup>) resulting from exposure of an employee to hyperbaric conditions including those that do not require recompression treatment (e.g., nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR part 1904. The notification must be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, in-patient hospitalizations, amputations, loss of an eye, or fatality, and submit a copy of the incident investigation (OSHA form 301) within 24 hours of the incident or 24 hours after becoming aware of a recordable case. In addition to the information required by the OSHA form 301, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification within 15 working days of the incident that Traylor JV informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the Baltimore/Washington DC Area Office within 15 working days and in writing, of any change in the compressed-air operations that affects Traylor JV's ability to comply with the conditions specified herein.

(d) Upon completion of the Blue Plains Tunnel project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the Baltimore/Washington DC Area Office.

**Note:** The evaluation report must contain summaries of: (1) The number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including

composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA 301 and 300 forms, and relevant medical diagnoses and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the conditions specified herein, inform the OTPCA and the Baltimore/Washington DC Area Office as soon as possible after it has knowledge that it will:

(i) Cease to do business;  
(ii) Change the location and address of the main office for managing the tunneling operations specified herein; or

(iii) Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this permanent variance by the same means required to inform them of its application for a variance.

2. OSHA must approve the transfer of the permanent variance to a successor company.

#### **Authority and Signature**

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to Section 29 U.S.C. 655(6)(d), Secretary of Labor's Order No. 1-2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1905.11.

#### **David Michaels,**

*Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. 2015-06975 Filed 3-26-15; 8:45 am]

**BILLING CODE 4510-26-P**

## **DEPARTMENT OF LABOR**

### **Office of the Secretary**

#### **Agency Information Collection Activities; Submission for OMB Review; Comment Request; Inorganic Arsenic Standard**

**ACTION:** Notice.

**SUMMARY:** The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, "Inorganic Arsenic Standard," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork

<sup>25</sup> See footnote 9.