(6) Instead of complying with section 9.1.1 of ASTM F2050–12, comply with the following:

(i) 9.1.1 The instructions shall contain statements, which address the warning statements in 8.3.2. For carriers intended for use as infant restraint devices in motor vehicles, the warning statement contained in the warning label depicted in 8.3.2.3 must also be included. In addition, the instructions shall include the following statements:

(ii) [Reserved]

(7) In addition to Figure 2, use the following:

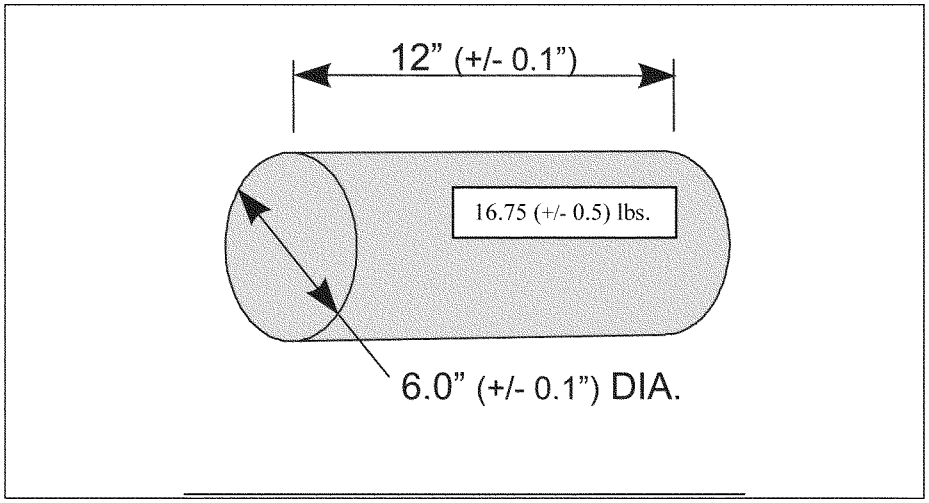

FIG. X Test Cylinder A

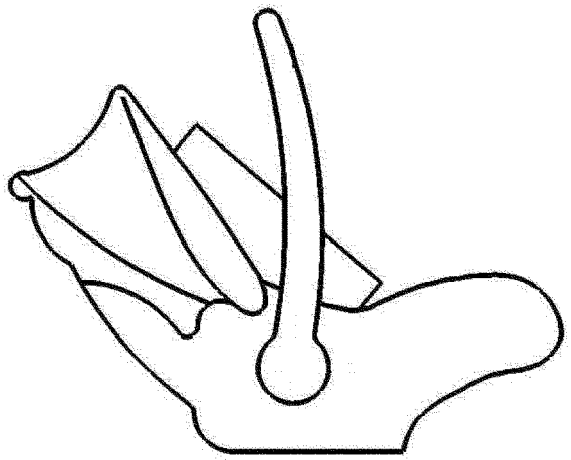

FIG. Y Test Cylinder Placed in Carrier

Dated: December 3, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–29584 Filed 12–7–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN89

Secondary Service Connection for Diagnosable Illnesses Associated With Traumatic Brain Injury

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its adjudication regulations concerning service-connection. This amendment is necessary to act upon a report of the National Academy of Sciences, Institute of Medicine (IOM), *Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury,* regarding the association between traumatic brain injury (TBI) and five diagnosable illnesses. The intended effect of this amendment is to establish that if a veteran who has a service-connected TBI also has one of these diagnosable illnesses, then that

illness will be considered service connected as secondary to the TBI.

DATES: *Effective Date:* Comments must be received by VA on or before February 8, 2013.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll free number.) Comments should indicate that they are submitted in response to ''RIN 2900–AN89—Secondary Service Connection for Diagnosable Illnesses Associated with Traumatic Brain Injury.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas J. Kniffen, Chief, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–9739. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: This document proposes to amend VA adjudication regulations (38 CFR Part 3) by revising 38 CFR 3.310 to add five diagnosable illnesses as secondary conditions which shall be held to be the proximate result of service-connected TBI.

Scientific Bases for This Rulemaking

In the National Academy of Science IOM Report, Gulf War and Health Volume 7: Long-Term Consequences of Traumatic Brain Injury, the IOM concluded there was ''sufficient evidence of a causal relationship'' (the IOM's highest evidentiary standard) between moderate or severe levels of TBI and diagnosed unprovoked seizures. The IOM found ''sufficient evidence of an association'' between moderate or severe levels of TBI and parkinsonism; dementias (which VA understands to include presenile dementia of the Alzheimer type and post-traumatic dementia); depression (which also was associated with mild TBI); and diseases of hormone deficiency that may result from hypothalamo-pituitary changes.

The medical literature that IOM reviewed included two primary studies and one secondary study on TBI and parkinsonism. One primary study involved 196 Parkinson's patients living in Olmstead County, Minnesota, and the second involved 93 pairs of male twins who were veterans from World War II. The secondary study involved 140 civilian Parkinson's patients in Boston, Massachusetts, who had suffered a TBI severe enough to cause loss of consciousness, blurred or double vision, dizziness, seizures, or memory loss. These three studies support a link between moderate or severe TBI and parkinsonism.

Medical literature supports a link between TBI and the two types of dementias listed above (presenile dementia of the Alzheimer type and post-traumatic dementia). Reported cases show that individuals with TBI often are diagnosed with dementia at ages younger than their early 50s and within 15 years of their injuries. As classic Alzheimer's disease strikes sufferers much later in life, the dementias suffered by TBI victims are unlikely to be classic Alzheimer's dementias. Classic Alzheimer's disease is the most common of many types of dementia that occur in older adults. It is difficult to conclude that Alzheimer's occurring at ages in the 60s or 70s is related to a distant TBI.

The IOM reviewed 4 primary studies of civilians and of troops serving in World War II and the current conflict in Iraq and five secondary studies of mood disorders including major depression. The primary studies generally supported an association between mild, moderate, or severe TBI and major depression within the first twelve months after the injury. Current research does not provide significant evidence to support association more than 12 months following mild TBI. Moderate or severe TBI appears to cause an elevated risk for depression (up to 50% in some research) for at least the first 3 years.

The IOM reviewed five studies on TBI and hypopituitarism, and five studies on TBI and growth hormone insufficiency. The studies generally showed increased risk of those conditions developing within months after a moderate or severe TBI and, although the effects in many cases were acute and eventually resolved, some long-term effects were observed. The medical literature reviewed by IOM supports a link between TBI and diseases of hormone deficiency resulting from hypothalamo-pituitary changes, when the disease manifests within 12 months of a moderate or severe TBI. The presence of other peripherally-mediated endocrinologic disorders (including, but not limited to diabetes mellitus) has no association with TBI.

After careful review of the findings of the NAS Report, Gulf War and Health Volume 7, the Secretary of Veterans Affairs has determined that the scientific evidence present in the NAS Report, Gulf War and Health Volume 7 and other information available to the Secretary indicates that a revision to VA regulations to add the five diagnosable illnesses as secondary conditions is warranted. The five diagnosable illnesses to be added are the following: (1) Parkinsonism following moderate or severe TBI; (2) unprovoked seizures following moderate or severe TBI; (3) dementias (to include presenile dementia of the Alzheimer type and post-traumatic dementia) within 15 years of moderate or severe TBI; (4) depression, if manifest within 3 years of moderate or severe TBI or within 12 months of mild TBI; and (5) diseases of hormone deficiency that result from hypothalamo-pituitary changes manifest within 12 months of moderate or severe TBI.

Section 501(a) of title 38, U.S. Code, establishes the Secretary of Veterans Affairs' general rulemaking authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by VA. Based on VA's analysis of the scientific evidence discussed in the IOM report as well as the IOM's finding of sufficient evidence of relationships between specific levels of TBI and certain diagnosable illnesses, and all other information available to the Secretary, we propose to amend 38 CFR 3.310 in order to incorporate five diagnosable illnesses as secondary conditions that are the proximate result of service-connected TBI.

The IOM also found associations between TBI and certain behavioral and social problems. These include diminished social relationships, aggressive behaviors, long-term unemployment, and premature death. Under 38 U.S.C. 1110, VA may only grant service connection ''[f]or disability resulting from personal injury suffered or disease contracted in line of duty * * *''. Similarly, § 1310(a) states, ''When any veteran dies * * * from a service-connected or compensable disability, the Secretary shall pay dependency and indemnity compensation to such veteran's surviving spouse, children, and parents.'' VA does not believe it is

necessary to establish new presumptions of service connection for these effects because they are not distinct physical or mental ''disabilities'' for VA compensation purposes. However, the behavioral, social, and occupational effects of TBI and related service-connected conditions may be considered in evaluating the severity of those conditions for compensation purposes as provided in provisions of VA's rating schedule.

In relevant part, § 3.310(a) states: ''[A] disability which is proximately due to or the result of a service-connected disease or injury shall be service connected. When service connection is thus established for a secondary condition, the secondary condition shall be considered a part of the original condition.'' We propose to revise § 3.310 by adding a new subsection (d)(1) that lists five diagnosable illnesses as secondary conditions that shall be held to be proximate results of service-connected TBI.

VA recognizes that not all those who suffer a TBI during military service seek immediate medical assistance and receive a medical assessment of the severity of the TBI. Therefore, proposed paragraph (d)(2) will clarify that neither severity levels nor time limits for manifesting secondary conditions as proximate causes of service-connected TBI shall preclude a veteran from establishing direct service connection under the generally applicable principles of service connection in 38 CFR 3.303 and 3.304.

Determination of the Severity of a TBI

VA and the Department of Defense have established a joint set of factors and criteria for classifying a TBI as mild, moderate, or severe. The factors and criteria were created by a team of physicians from VA and the Department of Defense who are experts on diagnosing and treating TBI. The factors are structural imaging (such as functional magnetic resonance imaging, diffusion tensor imaging, positron emission tomography (PET) scanning), duration of alteration of consciousness/mental state, duration of loss of consciousness, duration of post-traumatic amnesia, and score on the Glasgow Coma Scale. *See* Memorandum by Asst. Secretary of Defense for Health Affairs, ''Traumatic Brain Injury: Definition and Reporting,'' October 1, 2007. *See also* Compensation & Pension Service Training Letter 09–01, January 21, 2009.

We propose to include these severity criteria as a table in § 3.310(d)(3)(i). We also propose to explain in paragraph (d)(3)(ii) that the determination of the severity level is based on the TBI symptoms at the time of injury or shortly thereafter, rather than the current level of functioning. This provision is consistent with established medical principles for assessing the severity of TBI. *See* Memorandum by Asst. Secretary of Defense for Health Affairs, ''Traumatic Brain Injury: Definition and Reporting,'' October 1, 2007. *See also* Compensation & Pension Service Training Letter 09–01, January 21, 2009.

Some veterans may not meet all of the criteria within a particular severity level or may not have been examined for all the factors. We believe the simplest, most efficient, and fairest way to rank such veterans is to apply two rules: (1) VA will not require that a TBI meet all the criteria listed under a certain severity level to classify the TBI under that severity level; and (2) If a TBI meets the criteria relating to loss of consciousness, post-traumatic amnesia, or Glasgow Coma Scale in more than one severity level, then VA will rank the TBI at the highest of those levels. We propose to include these rules in paragraph (d)(3)(ii).

In some cases, it may not be clinically possible to determine the severity of a TBI (e.g., because of a lack of medical records contemporaneous with the injury or medical complications (e.g., medically induced coma)). In such cases, § 3.310(d) would not apply and the veteran's claim would be processed under § 3.310(a) which states that ''disability which is proximately due to or the result of a service-connected disease or injury shall be service connected.''

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary of Veterans Affairs hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule would not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' which requires review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined and it has been determined to be a significant regulatory action under the Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any year. This rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this proposed rule are 64.109, Veterans Compensation for Service-Connected Disability, and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on December 4, 2012, for publication.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Veterans, Vietnam.

Dated: December 5, 2012.

Robert C. McFetridge,

Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 3 as follows:

PART 3—ADJUDICATION

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Revise § 3.310 by adding paragraph (d), to read as follows:

§ 3.310 Disabilities that are proximately due to, or aggravated by, service-connected disease or injury.

* * * * *

(d) Traumatic brain injury. (1) In a veteran who has a service-connected traumatic brain injury, the following shall be held to be the proximate result of the service-connected traumatic brain injury (TBI), in the absence of clear evidence to the contrary:

(i) Parkinsonism following moderate or severe TBI;

(ii) Unprovoked seizures following moderate or severe TBI;

(iii) Dementias (presenile dementia of the Alzheimer type and post-traumatic dementia) if manifest within 15 years following moderate or severe TBI;

(iv) Depression if manifest within 3 years of moderate or severe TBI, or within 12 months of mild TBI; or

(v) Diseases of hormone deficiency that result from hypothalamo-pituitary changes if manifest within 12 months of moderate or severe TBI.

(2) Neither the severity levels nor the time limits in paragraph (d)(1) of this section preclude a finding of service connection for conditions shown by evidence to be proximately due to service-connected TBI. If a claim does not meet the requirements of paragraph (d)(1) with respect to the time of manifestation or the severity of the TBI, or both, VA will develop and decide the claim under generally applicable principles of service connection without regard to paragraph (d)(1).

(3)(i) For purposes of this section VA will use the following table for determining the severity of a TBI:

Mild	Moderate	Severe
Normal structural imaging LOC = 0–30 min	Normal or abnormal structural imaging LOC >30 min and <24 hours	Normal or abnormal structural imaging. LOC >24 hrs.
AOC = a moment up to 24 hrs	AOC >24 hours. Severity based on other criteria.	
PTA = 0–1 day GCS = 13–15	PTA >1 and <7 days GCS = 9–12	PTA > 7 days. GCS = 3–8.

Note: The factors considered are:
Structural imaging of the brain.
LOC—Loss of consciousness.
AOC—Alteration of consciousness/mental state.
PTA—Post-traumatic amnesia.
GCS—Glasgow Coma Scale. (For purposes of injury stratification, the Glasgow Coma Scale is measured at or after 24 hours.)

(ii) The determination of the severity level under this paragraph is based on the TBI symptoms at the time of injury or shortly thereafter, rather than the current level of functioning. VA will not require that the TBI meet all the criteria listed under a certain severity level in order to classify the TBI at that severity level. If a TBI meets the criteria relating to LOC, PTA, or GCS in more than one severity level, then VA will rank the TBI at the highest of those levels.

(Authority: 38 U.S.C. 501, 1110 and 1131)

[FR Doc. 2012–29709 Filed 12–7–12; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2010–0935, FRL–9760–5]

Approval and Promulgation of Air Quality Implementation Plans; State of Florida; Regional Haze State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve certain Best Available Retrofit Technology (BART) and reasonable progress determinations included in a regional haze state implementation plan (SIP) amendment submitted by the State of Florida, through the Florida Department of Environmental Protection (FDEP), on September 17, 2012. These BART and reasonable progress determinations are for sources that are subject to the Clean Air Interstate Rule (CAIR) and were initially included in a July 31, 2012, draft regional haze SIP amendment submitted by FDEP for parallel processing and re-submitted in final form as part of the State's September 17, 2012, regional haze SIP amendment. In this action, EPA also proposes to find that Florida's September 17, 2012, amendment corrects the deficiencies that led to the proposed May 25, 2012, limited approval and proposed December 30, 2011, limited disapproval of the State's entire regional haze SIP, and that Florida's SIP meets all of the regional haze requirements of the Clean Air Act (CAA). EPA is therefore withdrawing the previously proposed limited disapproval of Florida's entire regional haze SIP and proposing full approval. This proposed action supplements the May 25, 2012, proposed limited approval action by superseding the proposed limited approval and replacing it with a proposed full approval. EPA will take final action on