(1) In vitro diagnostic manufacturers; or

(2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

4. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Section 864.4010 is amended by revising paragraph (a) to read as follows:

§ 864.4010 General purpose reagent.

(a) A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labeled or otherwise intended for a specific diagnostic application. It may be either an individual substance, or multiple substances reformulated, which, when combined with or used in conjunction with an appropriate analyte specific reagent (ASR) and other general purpose reagents, is part of a diagnostic test procedure or system constituting a finished in vitro diagnostic (IVD) test. General purpose reagents are appropriate for combining with one or more than one ASR in producing such systems and include labware or disposable constituents of tests; but they do not include laboratory machinery, automated or powered systems. General purpose reagents include cytological preservatives, decalcifying reagents, fixative and adhesives, tissue processing reagents, isotonic solutions and pH buffers. Reagents used in tests for more than one individual chemical substance or ligand are general purpose reagents (e.g., *Thermus aquaticus* (TAQ) polymerase, substrates for enzyme immunoassay (EIA)).

* * * * *

6. New § 864.4020 is added to subpart E to read as follows:

§ 864.4020 Analyte specific reagents.

(a) *Identification.* Analyte specific reagents (ASR's) are antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. ASR's that otherwise fall within this definition are not within the scope of subpart E of this part when they are sold to:

(1) In vitro diagnostic manufacturers; or

(2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

(b) *Classification.* (1) Class I (general controls). Except as described in paragraphs (b)(2) and (b)(3) of this section, these devices are exempt from the premarket notification requirements in part 807, subpart E of this chapter.

(2) Class II (special controls/guidance documents), when the analyte is used in blood banking tests that have been classified as class II devices (e.g., certain cytomegalovirus serological and treponema pallidum nontreponemal test reagents). Guidance Documents:

1. ''Specifications for Immunological Testing for Infectious Disease; Approved Guideline,'' NCCLS Document I/LA18–A, December 1994.

2. ''Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Tentative Guideline,'' NCCLS Document KGP10–T, December 1993.

3. ''Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium spp,'' FDA, July 6, 1993, and its ''Attachment 1,'' February 28, 1994.

4. ''Draft Review Criteria for Nucleic Acid Amplification-Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms,'' FDA, July 6, 1993.

5. The Center for Biologics Evaluation and Research, FDA, ''Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus, Type I'' (54 FR 48943, November 28, 1989).

(3) Class III (premarket approval), when:

(i) The analyte is intended as a component in a test intended for use in the diagnosis of a contagious condition that is highly likely to result in a fatal outcome and prompt, accurate diagnosis offers the opportunity to mitigate the public health impact of the condition (e.g., human immunodeficiency virus (HIV/AIDS)or tuberculosis (TB)); or

(ii) The analyte is intended as a component in a test intended for use in donor screening for conditions for which FDA has recommended or required testing in order to safeguard the blood supply or establish the safe use of blood and blood products (e.g., tests for hepatitis or tests for identifying blood groups).

(c) *Date of 510(k), or date of PMA or notice of completion of a product development protocol is required.* (1) Preamendments ASR's; No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(3) of this section. See § 864.3.

(2) For postamendments ASR's; November 23, 1998.

(d) *Restrictions.* Restrictions on the sale, distribution and use of ASR's are set forth in § 809.30 of this chapter.

Dated: November 13, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–30334 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 657

RIN 2125–AE20

Truck Size and Weight; Office of Management and Budget Control Number and Expiration Date

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This document adopts a technical amendment to the regulations at 23 CFR part 657 to provide the Office of Management and Budget (OMB) control number for the Federal Highway Administration's (FHWA) collection of information from the States about their size and weight enforcement programs and explains the significance of referencing that number in 23 CFR part 657.

EFFECTIVE DATE: November 21, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Klimek, Office of Motor Carrier Information Analysis, (202) 366–2212, or Mr. Charles Medalen, Office of the Chief Counsel, (202) 366–1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.s.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Federal law requires each State to certify to the Secretary of Transportation before January 1 of each year that it is enforcing: (1) Federal law regarding (i) vehicle weight on the Interstate System and (ii) vehicle size on the former Federal-aid primary, secondary and urban systems; and (2) State size and weight laws on the former Federal-aid primary, secondary and urban systems [23 U.S.C. 141(a)].

If the weight laws that apply on the Interstate System in a State are not consistent with the Federal standard [23 U.S.C. 127], the State is subject to the withholding of its National Highway System (NHS) funds. If the size laws that apply on the former Federal-aid systems mentioned above (now designated the National Network [NN] for trucks) are not consistent with the Federal standard [49 U.S.C. 31111–31114], the State is subject to injunctive action in Federal court. If the State does not file a certification at all, or if the certification fails to demonstrate adequate enforcement of State size and weight laws, the Federal-aid funds that would otherwise be apportioned under 23 U.S.C. 104 must be reduced by 10 percent [23 U.S.C. 141(b)(2)].

The FHWA regulations implement these statutory mandates by requiring each State annually to file: (1) an enforcement plan setting forth measurable goals; and (2) a certification that discusses the consistency of State law with Federal requirements and the State's success in achieving its enforcement goals for the previous fiscal year (23 CFR part 657).

Under the Paperwork Reduction Act of 1995 [44 U.S.C. 3501 *et seq.*], regulations which impose an information collection requirement must be authorized by the Office of Management and Budget (OMB). The information collection requirements of 23 CFR part 657 are currently authorized under OMB Control Number 2125–0034, which is valid until May 31, 2000. The FHWA, however, inadvertently failed to list the control number in part 657 or to inform the States of its legal significance, as required by OMB rules [5 CFR 1320.5(b)]. When a currently valid OMB control number is not displayed, failure to submit to the FHWA an annual enforcement plan or certification with the form and content specified by part 657 would not be grounds for withholding 10 percent of a State's Federal-aid highway funds [44 U.S.C. 3512(a)]. The reporting requirement [23 U.S.C. 141(a)–(b)] would remain in effect, but any kind of ''certification'' that met the terms of the statute would be adequate.

The FHWA is therefore amending 23 CFR part 657 to add a note at the end stating that the information collection requirements of that part have been approved by OMB. The agency has held OMB approvals for the information collection requirements associated with part 657 since the Paperwork Reduction Act became effective. The FHWA finds good cause pursuant to 5 U.S.C. 553(b) to dispense with prior notice and an opportunity for public comment on this document. Part 657 was adopted through notice and comment rulemaking, and the FHWA applied for and received the OMB control number in the normal manner. This amendment simply displays the control number, as required by OMB rules, and is not separately subject to notice and comment rulemaking procedures. The agency also finds good cause under 5 U.S.C. 553(d)(3), for the reasons given above, to make this amendment to part 657 final upon publication in the **Federal Register**.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is neither a significant regulatory action within the meaning of Executive Order 12866 nor significant within the meaning of Department of Transportation regulatory policies and procedures. It merely adds the OMB control number to the regulations requiring States to submit information about their size and weight programs. It is anticipated that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Since it deals with regulations applicable to the States, it should have no effect on any small entities. Based on this evaluation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

The information collection requirements necessary for States to be able to certify that they are enforcing their size and weight laws, as provided in 23 CFR 657, have been approved by the OMB under control number OMB 2125–0034 in accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The approval expires on May 31, 2000.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulatory identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects 23 CFR 657

Grant programs—transportation, Highways and roads, Motor carrier size and weight.

Issued on: November 7, 1997.

Gloria J. Jeff,

Acting Administrator.

In consideration of the foregoing, the FHWA amends title 23 CFR part 657 as set forth below:

PART 657—[AMENDED]

1. The authority citation for 23 CFR part 657 is revised to read as follows:

Authority: Sec. 123, Pub. L. 95–599, 92 Stat. 2689; 23 U.S.C. 127, 141, and 315; 49 U.S.C. 31111, 31113, and 31114; sec. 1023, Pub. L. 102–240, 105 Stat. 1914; and 49 CFR 1.48(b)(19), (b)(23), (c)(1), and (c)(19).

2. Part 657 is amended by adding the following note:

Note: The recordkeeping requirements contained in this part have been approved by the Office of Management and Budget under control number 2125–0034.

[FR Doc. 97–30655 Filed 11–20–97; 8:45 am]

BILLING CODE 4910–22–P