PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

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

2. Section 872.3940 is amended by revising paragraph (c) to read as follows:

§ 872.3940 Total temporomandibular joint prosthesis.

* * * * *

- (c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976. Any other total temporomandibular joint prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.
- 3. Section 872.3950 is amended by revising paragraph (c) to read as follows:

§ 872.3950 Glenoid fossa prosthesis.

* * * * *

- (c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any glenoid fossa prosthesis that was in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to a glenoid fossa prosthesis that was in commercial distribution before May 28, 1976. Any other glenoid fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.
- 4. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

(c) Date PMA or notice of completion of a PDP is required. (1) Except as described in paragraph (c)(2) of this section, a PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that

was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

- (2) No effective date has been established of the requirement for premarket approval for any mandibular condyle prosthesis intended to be implanted in the human jaw for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle. See § 870.3 of this chapter.
- 5. Section 872.3970 is amended by revising paragraph (c) to read as follows:

§ 872.3970 Interarticular disc prosthesis (interpositional implant).

* * * * *

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to an interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976. Any other interarticular disc prosthesis (interpositional implant) shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: November 23, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–34483 Filed 12–29–98; 8:45 am] BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. 98-3467]

RIN 2125-AE36

Truck Size and Weight; National Network; North Dakota

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: This document modifies the National Network for commercial motor

vehicles by adding a route in North Dakota. The National Network was established by a final rule on truck size and weight published on June 5, 1984, as since modified. This rulemaking adds one segment to the National Network as requested by the State of North Dakota. DATES: This rule is effective January 29, 1999.

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

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. DOT Dockets, Room PL-401, by using the universal resource locator (URL): http://dms.dot.gov. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202)512–1661. Internet users may reach the **Federal Register**'s home page at: http://www.nara.gov/fedreg and the Government Printing Office's database at: http://www.access.gpo.gov/nara.

Background

The National Network of Interstate highways and federally-designated routes, on which commercial vehicles with the dimensions authorized by the Surface Transportation Assistance Act of 1982 (STAA), 49 U.S.C. 31111, 31113–31114, may operate, was established by a final rule published in the **Federal Register** on June 5, 1984 (49 FR 23302), as subsequently modified. These highways are located in each State, the District of Columbia, and Puerto Rico. Routes on the National Network are listed in appendix A of 23 CFR Part 658.

Procedures for the addition and deletion of routes are outlined in 23 CFR 658.11 and include the issuance of a notice of proposed rulemaking (NPRM) before final rulemaking.

In accordance with these procedures, the State of North Dakota, under authority of the Governor, requested the addition of one segment to the National Network. The segment requested is generally described as ND Highway 32 from the west junction of ND Highway 13 north to Interstate 94, a distance of approximately 56 miles. The segment was reviewed by State and FHWA offices for general adherence to the criteria of 23 CFR 658.9 and found to provide for the safe operation of larger commercial vehicles and for the needs of interstate commerce. A notice of proposed rulemaking (NPRM) listing North Dakota's proposed change to the National Network was published on May 18, 1998 (63 FR 27228). The closing date for comments was July 17, 1998.

Discussion of Comments

Only one comment was received. The Melroe Company supports the request to include Highway 32 from the west junction of ND Highway 13 north to Interstate 94 in the National Network. This carrier has operated double trailers for 13 years and sees the addition of Hwy 32 to the network as an opportunity to reduce the amount of travel by its vehicles on 2-lane roads. Presently Melroe vehicles must travel 119 miles via North Dakota routes 13, 1, 11, and 281 to reach Interstate 94 via National Network routes. The addition of ND route 32 will reduce the travel from Gwinner to Interstate 94 to 54 miles, a reduction of 65 miles per trip.

Modifications of the National Network

Overall we find that the record here, including the information introduced by the State of North Dakota together with comments submitted by the Melroe Company, supports the addition of the involved segment of Highway 32 to the National Network for purposes of enhanced safety, convenience, and support of interstate commerce. Accordingly, the FHWA will modify the regulations at 23 CFR Part 658 by adding the requested route for North Dakota

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

The FHWA has determined that this action does not constitute a significant regulatory action within the meaning of E.O. 12866, nor is it considered significant under the regulatory policies and procedures of the DOT. It is anticipated that the economic impact of

this rulemaking will be minimal. This rulemaking provides a technical amendment to 23 CFR 658, adding a certain highway segment in accordance with statutory provisions. This segment represents a very small portion of the National Network and has a negligible impact on the prior system. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. As noted previously, this rulemaking provides a technical amendment to 23 CFR 658, adding a certain highway segment in accordance with statutory provisions. This segment represents a very small portion of the National Network and has a negligible impact on the prior system. This rulemaking will allow motor carriers, including small carriers, access to a highway segment previously not available to them.

Based on its evaluation of this rule, the FHWA certifies that this action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

This rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rulemaking relates to the Federal-aid Highway Program which is a financial assistance program in which State, local, or tribal governments have authority to adjust their program in accordance with changes made in the program by the Federal government, and thus is excluded from the definition of Federal mandate under the Unfunded Mandates Reform Act of 1995.

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 the rule 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 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal Programs and activities do not apply to this program.

Paperwork Reduction Act

This document does not contain information collection requirements for the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

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 regulation 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 contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 658

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

Issued on: December 22, 1998.

Kenneth R. Wykle,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA amends title 23, Code of Federal Regulations, Chapter I, appendix A to Part 658 for the State of North Dakota as set forth below:

PART 658—TRUCK SIZE AND WEIGHT, ROUTE DESIGNATIONS—LENGTH, WIDTH AND WEIGHT LIMITATIONS

1. The authority citation for 23 CFR part 658 is revised to read as follows:

Authority: 23 U.S.C. 127 and 315; 49 U.S.C. 31111—31114; 49 CFR 1.48.

2. Appendix A to Part 658 is amended for the State of North Dakota by adding a new route listing entry after the listing for ND 13, ND 1 S. Jct., MN State Line to read as follows:

Appendix A to Part 658—National Network—Federally-Designated Routes

* * * * *

NORTH DAKOTA

Route	From							То
	*	*	*	*	*	*	*	
ND 32	West Junction of ND Highway 13							I-94
	*	*	*	*	*	*	*	

[FR Doc. 98–34636 Filed 12–29–98; 8:45 am] BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602 [TD 8801] RIN 1545-AU39

Arbitrage Restrictions on Tax-Exempt Bonds

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

summary: This document contains final regulations on the arbitrage restrictions applicable to tax-exempt bonds issued by State and local governments. Changes to applicable law were made by the Tax Reform Act of 1986. These regulations affect issuers of tax-exempt bonds and provide guidance for complying with the arbitrage regulations.

DATES: Effective Date: These regulations are effective on March 1, 1999.

Applicability Date: These regulations are applicable to bonds sold on or after March 1, 1999.

Issuers may apply these regulations to bonds sold on or after December 30, 1998 and before March 1, 1999.

FOR FURTHER INFORMATION CONTACT: David White, 202–622–3980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1490. Responses to these collections of information are required to obtain the benefits of a safe harbor.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated annual burden per record keeper varies from .75 hour to 2 hours, depending on individual

circumstances, with an estimated average of 1 hour.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

These final regulations contain amendments to the income tax regulations (26 CFR Part 1) under section 148 of the Internal Revenue Code of 1986 (Code). Section 148 provides rules addressing the use of proceeds of tax-exempt State and local bonds to acquire higher-yielding investments. On June 18, 1993, final regulations (TD 8476) relating to the arbitrage restrictions and related rules under sections 103, 148, 149, and 150 were published in the Federal Register (58 FR 33510). Corrections to these regulations were published in the Federal Register on August 23, 1993 (58 FR 44451), and May 11, 1994 (59 FR 24350).

On June 27, 1996, a notice of proposed rulemaking (FI-28-96) relating to the arbitrage restrictions was published in the Federal Register (61 FR 33405). The proposed regulations provide a rebuttable presumption for establishing fair market value for United States Treasury obligations that are purchased other than directly from the United States Treasury. In addition, the proposed regulations provide a rebuttable presumption that a solicitation that meets certain requirements is a bona fide solicitation for the guaranteed investment contract safe harbor of § 1.148–5(d)(6)(iii). A public hearing was held on Thursday, October 24, 1996, and written comments were received. After consideration of all the comments, the regulations proposed

by FI–28–96 are, with modifications, adopted by revision to \S 1.148–5(d)(6)(iii). The changes are discussed below.

Explanation of Provisions

A. In General

Due to concerns regarding the fair market purchase price of United States Treasury obligations purchased other than directly from the United States Treasury, the proposed regulations provide a rebuttable presumption for establishing fair market value. The proposed regulations generally apply the principles underlying the existing safe harbor in the arbitrage regulations for establishing fair market value for guaranteed investment contracts.

The proposed regulations also provide a rebuttable presumption that a solicitation meeting the requirements of the proposed regulations will be a bona fide solicitation for the guaranteed investment contract safe harbor of existing § 1.148–5(d)(6)(iii).

Modifications to the proposed regulations have been made to clarify various technical aspects in response to comments received.

B. Safe Harbor

Commentators noted that a rebuttable presumption in the proposed regulations for purchases of United States Treasury obligations provides a lower level of protection to issuers than the safe harbor applicable to guaranteed investment contracts. Commentators generally requested that the final regulations provide a safe harbor for the purchase of United States Treasury obligations.

The final regulations create a safe harbor for all investments covered by the regulations, provided that the issuer receives at least three bids as required by the regulations. The premise of the final regulations is that a bidding procedure satisfying the requirements of the final regulations will produce a price that equals fair market value. If the requirements of the final regulations are not in fact met, no assumption can be made about the relationship of the price paid to fair market value. However, all reasonable and prudent actions taken by the issuer under the circumstances may be considered in determining whether the issuer paid fair market value.