not impose an additional duty or burden on any person but rather promote consistency between the additional standards and the requirement of the general biologics regulations, as amended in 1975. These regulations were promulgated by the Commission on February 27, 1976, and may justify further modification of this procedure.

The Commissioner has carefully considered the inflation impact of this regulation and no major inflation impact has been found, as defined in Executive Order 11221, OMB Circular A-107, and interim guidelines issued April 1, 1975, by the Department of Health, Education, and Welfare.

Therefore, under the Public Health Service Act, sec. 351, 1st sec., 702 as amended (42 U.S.C. 262) and under authority delegated to the Commissioner (21 C.F.R. sec. 1.210), Subchapter P of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

§ 610.12 [Amended]

1. In § 610.12 Sterility delete paragraphs (g)(5) and redesignate existing paragraphs (g)(6) through (10) as (g)(5) through (9).

PART 630—ADDITIONAL STANDARDS FOR VACCINE VACCINES

2. In § 630.74 by revise paragraphs (a) and (b) to read as follows:

§ 630.74 Tests for safety.

(a) **Clostridium tetani**. A 0.1 milliliter sample representative of the homogenized vaccine harvested in several stages shall be tested for the presence of **Clostridium tetani** in the following manner: Prior to the addition of preservatives other than glyceroi, the test sample shall be inoculated into freshly heated Fluid Thoglycollate Medium using a ratio of inoculum to culture medium sufficient for optimal bacterial growth. The test vessels shall be incubated at 35° to 37° C and observed daily for 15 days for evidence of bacterial growth. Within 24 to 48 hours of the first appearance of anaerobic growth, 1.0 milliliter samples from each vessel showing growth shall be inoculated subcutaneously into each of at least three mice weighing not more than 20 grams and three mice weighing not more than 350 grams. Additional groups of animals shall be inoculated 9 days after the original plant if growth appears and provided the first set of test animals is negative. All test animals shall be observed daily for at least 6 days. If there is any evidence of the presence of heat resistant pathogenic anaerobes, the viral harvest may not be used in the manufacture of Smallpox Vaccine.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

3. In § 640.2 revise paragraph (b) to read as follows:

§ 640.2 General requirements.

(b) **Periodic check on sterility technique**. Were blood is collected in an open system, that is, where the blood container is entered, at least one container of such blood that upon visual examination appears normal shall be tested each month between the 16th and 24th day after collection, as a continuing check on technique of blood collection, as follows:

The test shall be performed with a total sample of no less than 10 milliliters of blood and a total volume of Fluid Thoglycollate Medium 10 times the volume of the sample of blood. The test sample shall be inoculated into one or more test vessels in a ratio of blood to medium of 1 to 10 for each vessel, mixed thoroughly, incubated for 7 to 9 days at a temperature of 30° to 32° C, and examined for evidence of growth of microorganisms every workday throughout the test period. If growth is observed in any test vessel, the test shall be repeated to rule out faulty test procedure, using another sample of blood from either (1) the container from which the initial test sample was taken; (2) the residual cells or plasma from that blood; or (3) two different containers of blood, each 18 to 24 days old and each tested separately. The formula for Fluid Thoglycollate Medium shall be as prescribed in § 610.12(e) (1) and (ii) of this chapter. In lieu of performing one test using an incubation temperature of 30° to 32° C, two tests may be performed. Each in all respects as prescribed in this paragraph, one at an incubation temperature of 18° to 22° C and one at an incubation temperature of 33° to 35° C. A different test may be performed provided that prior to the performance of such a test, a manufacturer submits data that the Commissioner of Food and Drugs finds adequate to establish that the different test is equal or superior to the test herein prescribed as a check on sterility technique, and makes the finding a matter of official record.

PART 660—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

4. In § 660.2 revise paragraph (a)(2) to read as follows:

§ 660.2 Tests.

(a) **(2)** For lots consisting of no more than 5 final containers, the final container test shall be performed in accordance with § 610.12(g) (6) of this chapter using the sample therein prescribed for a sample of no less than 0.25 ml. of product from each final container, divided in approximately equal proportions for testing using Fluid Thoglycollate and Soybean Cassein Digest Media. The test sample in the later alternative method may be an overfill in the final container.

**Effective date.** This regulation shall be effective on January 28, 1976.


SAM D. FINZ,
Associate Commissioner for Compliance.

[FR Doc.76-2429 Filed 1-27-76; 8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1208—SCHEDULES OF CONTROLLED SUBSTANCES

Peysota

On April 22, 1975, the Administrator of the Drug Enforcement Administration
RULES AND REGULATIONS

Title 41—Public Contracts and Property Management
CHAPTER 8—VETERANS ADMINISTRATION
PART 8-14—INSPECTION AND ACCEPTANCE

Inspection at Destination

Part 8-14, Inspection and Acceptance, Chapter 8, Title 41, Code of Federal Regulations, is amended as set forth below.

The supply depots are authorized to correct packaging, packing, or marking not in accordance with contract requirements when the cost of correcting a partial receipt or projected cost of correcting total receipt does not exceed $50. Section 8-14.105-3 is amended to raise depot authorization of packaging, packing, or marking corrections to $100. In addition, organizational titles have been updated and minor editorial changes were made to reflect agency policy of using precise terms denoting gender.

It is the general policy of the Veterans Administration to allow time for interested parties to participate in the rule making process (§ 1.12, Title 38, Code of Federal Regulations). However, the amendments herein concern agency procedure and practices. Therefore, the public comment process is deemed unnecessary in this instance.

1. In § 8-14.105-3, paragraph (b) is revised to read as follows:

§ 8-14.105-3 Inspection at destination.

(b) VA supply depots will report all instances of noncompliance to the contracting officer on VA Form 10-2055, Sample Transmittal Sheet and Inspection Report. The supply depots are authorized to correct packaging, packing, or marking not in accordance with contract requirements when the cost of correcting a partial receipt or projected cost of correcting total receipt does not exceed $100. When projected costs exceed $100, authorization will be obtained from the contracting officer prior to taking corrective action. The corrections made and the actual amount to be charged to the vendor will be shown on the reverse of VA Form 10-2055.

2. In § 8-14.105-51, paragraph (b) (4) is revised to read as follows:

§ 8-14.105-51 Inspection of subsistence.

(b) When either the Department of Agriculture or the Department of Commerce is indicated as the inspection activity, the solicitation will also provide that the contractor is responsible for:

(4) Furnishing samples for inspection at his/her expense.

3. In § 8-14.105-53, paragraph (b) introduction and paragraph (c) are revised to read as follows:

(b) On items bearing lot numbers, one unit will be selected from each lot to be tested, unless otherwise specified. Contracts will require that the contractor’s shipping document or packing list indicate the lot numbers of items shipped to each depot on the contract. To reduce handling and transportation costs, samples or items received at more than one location will be submitted as follows:

(3) The VA Supply Depot, Bell, Calif., will submit samples from lots not received at Mines or Somerville.


These regulations are effective January 28, 1976.

Approved: January 22, 1976.

By direction of the Administrator.

[SEAL]

ODELL W. VAUGHN,
Deputy Administrator.

[FR Doc.76-2437 Filed 1-27-76; 8:45 am]

Title 49—Transportation

CHAPTER V—NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

[Docket No. 73-3; Notice 06]

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

School Bus Passenger Seating and Crash Protection

This notice establishes a new motor vehicle safety Standard No. 222, School Bus Seating and Crash Protection, that specifies seating, restraining barrier, and impact zone requirements for school buses.

The Motor Vehicle and Schoolbus Safety Amendments of 1974, Pub. L. 93-492, directed the issuance of a school bus seating systems performance standard (and other standards governing vehicle performance). The NHTSA had already issued two proposals for school bus seating systems prior to enactment of the 1974 Amendments (the Act) (38 FR 4776, February 23, 1973) (39 FR 27585, July 30, 1974) and subsequently published two additional proposals (40 FR 17555, April 22, 1975) (40 FR 47141, October 8, 1975). Each aspect of the requirements was fully considered in the course of this rulemaking activity. Comments received in response to the most recent proposal were limited to a few aspects of the standard.

The largest number of comments we received on the requirement that school bus passenger seats be equipped with seat belt anchors at each seating position. The standard relies on compartmentalization between well-padded and well-constructed seats to provide occupant protection on school buses (other than van-type buses). At the same time, seat belt anchors were proposed so that a greater measure of protection could be gained if a particular user chose to use the anchors by installation of