surgical suture, and substantially equivalent devices of this generic type, from class III to class II. FDA identified the following FDA recognized consensus standards and labeling as special controls for the device:

1. United States Pharmacopoeia (USP) 21:
   a. Monograph for Nonabsorbable Surgical Sutures;
   b. Suture—Diameter <861>;
   c. Suture—Needle Attachment <871>;
   d. Tensile Strength <881>.

2. Labeling:
   a. Contraindication: “This device is contraindicated for use in ophthalmic and neural tissues and for use in microsurgery.”
   b. “For Single Use Only.”
   c. If the marketed suture has a different diameter than the diameter specified in USP 21—Suture Diameter <861>, then a tabular comparison of its diameter and USP suture sizes should be included in the labeling.

Accordingly, as required by 21 CFR 860.136(b)(6) of the regulations, FDA is announcing the reclassification of the generic nonabsorbable ePTFE surgical suture from class III into class II. In addition, FDA is codifying the reclassification of the device by adding new §878.5040.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the notice is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public. Therefore, no burden is placed on the public.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:


2. Section 878.5035 is added to subpart E to read as follows:

§878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.

(a) Identification. Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).
Introduction

Section 18 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 651, et seq., (the “Act”) provides that States which desire to assume responsibility for the development and enforcement of occupational safety and health standards may do so by submitting, and obtaining Federal approval of, a State plan. Procedures for State Plan submission and approval are set forth in regulations at 29 CFR Part 1902. If the Assistant Secretary, applying the criteria set forth in section 18(c) of the Act and 29 CFR 1902.3 and .4, finds that the plan provides or will provide for State standards and enforcement which are “at least as effective” as Federal standards and enforcement, “initial approval” is granted. A State may commence operations under its plan after this determination is made, but the Assistant Secretary retains discretionary Federal enforcement authority during the initial approval period as provided by section 18(e) of the Act. A State plan may receive initial approval even though, upon submission, it does not fully meet the criteria set forth in §§ 1902.3 and 1902.4 if it includes satisfactory assurances by the State that it will take the necessary “developmental steps” to meet the criteria within a three-year period (29 CFR 1902.2(b)). The Assistant Secretary publishes a “certification of completion of developmental steps” when all of a State’s developmental commitments have been satisfactorily met (29 CFR 1902.34).

When a State plan that has been granted initial approval is developed sufficiently to warrant a suspension of concurrent Federal enforcement activity, it becomes eligible to enter into an “operational status agreement” with OSHA (29 CFR 1954.3(f)). A State must have enacted its enabling legislation, promulgated State standards, achieved an adequate level of qualified personnel, and established a system for review of contested enforcement actions. Under these voluntary agreements, concurrent Federal enforcement will not be initiated with regard to Federal occupational safety and health standards in those issues covered by the State plan, where the State program is providing an acceptable level of protection.

Following the initial approval of a complete plan, or the certification of a developmental plan, the Assistant Secretary must monitor and evaluate actual operations under the plan for a period of at least one year to determine, on the basis of actual operations under the plan, whether the criteria set forth in section 18(c) of the Act and 29 CFR 1902.37 are being applied.

An affirmative determination under section 18(e) of the Act (usually referred to as “final approval” of the State plan) results in the relinquishment of authority for Federal concurrent enforcement jurisdiction in the State with respect to occupational safety and health issues covered by the plan (29 U.S.C. 667(e)). Procedures for section 18(e) determinations are found at 29 CFR part 1902, Subpart D. In general, in order to be granted final approval, actual performance by the State must be “at least as effective” overall as the Federal OSHA program in all areas covered under the State plan.

An additional requirement for final approval consideration is that a State must meet the compliance staffing levels, or benchmarks, for safety inspectors and industrial hygienists established by OSHA for that State. This requirement stems from a court order by the U.S. District Court for the District of Columbia pursuant to the U.S. Court of Appeals’ decision in AFL–CIO v. Marshall, 570 F.2d 1030 (D.C. Cir 1978), that directed the Assistant Secretary to calculate for each State the number of enforcement personnel needed to assure a “fully effective” enforcement program.

The last requirement for final approval consideration is that a State must participate in OSHA’s Integrated Management Information System (IMIS). This is required so that OSHA can obtain the detailed program performance data on a State necessary to make an objective continuing evaluation of whether the State performance meets the statutory and regulatory criteria for final and continuing approval.

History of the Nevada Plan and of Its Compliance Staffing Benchmarks

Nevada Plan

A history of the Nevada State plan, a description of its provisions, and a discussion of the compliance staffing benchmarks established for Nevada was contained in the November 16, 1999, Federal Register notice (64 FR 62138) proposing that final approval under Section 18(e) of the Act be granted. The Nevada State plan was submitted on December 12, 1972, initially approved on December 28, 1973 (39 FR 1008), certified as having completed all developmental steps on August 13, 1981 (42 FR 42844), concurrent Federal enforcement jurisdiction suspended on December 9, 1981 (47 FR 25323), and revised compliance staffing benchmarks for Nevada were approved on September 11, 1987 (52 FR 34381).
the Nevada Division of Industrial Relations in Carson City, Nevada. Summaries of the November 16 notice, with an invitation for public comments, were published in Nevada on November 24, 1999 in the Las Vegas Review-Journal and on November 26, 1999 in the Elko Daily Free Press, Reno Gazette Journal and Nevada Appeal.

The November 16 notice invited interested persons to submit by December 16 written comments and views regarding the Nevada plan and whether final approval should be granted. An opportunity to request an informal public hearing also was provided. Four (4) comments were received in response to this proposal; none requested an informal hearing.

Summary and Evaluation of Comments

OSHA has encouraged interested members of the public to provide information and views regarding operations under the Nevada plan to supplement the information already gathered during OSHA monitoring and evaluation of plan administration. In response to the November 16 proposal, OSHA received comments from: Robert Ostrovsky, President, Ostrovsky and Associates, member and former Chairman, Department of Industrial Relations (DIR) Advisory Board [Ex. 3–1]; Linda M. Rogers, Vice-Chairman, DIR Advisory Board [Ex. 3–2]; John S. Rogers, CEO, Pacific Matrix Financial Corporation and former Chairman, Nevada Occupational Safety and Health Review Board [Ex. 3–3]; and Danny L. Thompson, Executive Secretary-Treasurer, Nevada State AFL-CIO [Ex. 3–4]. All four commenters expressed unqualified support for final approval. All of these comments indicated that the State has established and operates an effective safety and health program and that the State has been effective in protecting employees in Nevada. Specifically, the commenters commended the State program for, among other things: its automatic adoption of Federal standards; requirements in excess of those under Federal OSHA; and, in such areas as pre-construction safety conferences and standards for ammonium perchlorate and tower cranes; and effective staffing.

Findings and Conclusions

As required by 29 CFR 1902.41, in considering the granting of final approval to a State plan, OSHA has carefully and thoroughly reviewed all information available to it on the actual operation of the Nevada State plan. This information included all previous evaluation findings since certification of completion of the State plan’s developmental steps, especially data for the period July 1, 1995 through March 31, 1999, and information presented in written submissions. Findings and conclusions in each of the areas of performance are as follows:

1. Standards. Section 18(c)(2) of the Act requires State plans to provide for occupational safety and health standards which are at least as effective as Federal standards. Such standards where not identical to the Federal must be promulgated through a procedure allowing for consideration of all pertinent factual information and participation of all interested persons (29 CFR 1902.4(b)(2)(iii)); must, where dealing with toxic materials or harmful physical agents, assure employee protection throughout their or her working life (29 CFR 1902.4(b)(2)(i)); must provide for furnishing employees appropriate information regarding hazards in the workplace through labels, posting, medical examinations, etc. (29 CFR 1902.4(b)(2)(vi)); must require suitable protective equipment, technological controls, monitoring, etc. (29 CFR 1902.4(b)(2)(vii)); and, where applicable to a product, must be required by compelling local conditions and not pose an undue burden on interstate commerce (29 CFR 1902.3(c)(2)).

As documented in the approved Nevada State plan and OSHA’s evaluation findings made a part of the record in this 18(e) determination proceeding, and as discussed in the November 16 notice, the Nevada plan provides for standards and amendments thereto which are identical to Federal standards. The State’s laws and regulations, previously approved by OSHA and made a part of the record in this proceeding, include provisions addressing all of the structural requirements for State standards set out in 29 CFR Part 1902.

In order to qualify for final State plan approval, a State program must be found to have adhered to its approved procedures (29 CFR 1902.37(b)(2)); to have timely adopted identical or at least as effective standards, including emergency temporary standards and standards amendments (29 CFR 1902.37(b)(3)); to have interpreted its standards in a manner consistent with Federal interpretations and thus to demonstrate that in actual operation State standards are at least as effective as the Federal (29 CFR 1902.37(b)(4)); and to correct any deficiencies resulting from administrative or judicial challenge of State standards (29 CFR 1902.37(b)(5)).

As noted in the 18(e) Evaluation Report and summarized in the November 16, 1999 Federal Register notice, Nevada has adopted standards in a timely manner which are identical to Federal standards.

The Nevada plan provides for the automatic adoption of standards which are identical to Federal standards. A new standard becomes effective in Nevada on the effective date of the Federal standard. The State may adopt alternative standards and has adopted some standards which do not have Federal counterparts, such as standards concerning ammonium perchlorate and tower cranes. Nevada also has regulations requiring pre-construction safety conferences with the Division of Industrial Relations for certain types of construction projects.

The State also requires employers with more than 10 employees to implement safety and health programs, including a safety and health committee for employers with more than 25 employees. For issues where OSHA is considering issuing a rule, as in the case of safety and health committee size, the agency does not take action to decide whether the State plan requirements are at least as effective until the Federal action is complete. Nor can OSHA review this requirement for compliance with the National Labor Relations Act (NLRA), which is independently administered by the National Labor Relations Board. The Board’s General Counsel has noted in a written opinion that committee requirements under State law do not amount to a per se violation of the NLRA; however, the General Counsel has pointed out that employers must comply with State laws in a manner which does not constitute an unfair labor practice under the NLRA.

Nevada’s standards adoption process continued to meet the six-month time frame for adoption of OSHA standards requiring State action during the section 18(e) evaluation period.

Where a State adopts Federal standards, the State’s interpretation and application of such standards must ensure consistency with Federal interpretation and application. OSHA’s monitoring has found that the State’s application of its standards is comparable to Federal standards application. No challenges to State standards have occurred in Nevada.

Therefore, in accordance with section 18(c)(2) of the Act and the pertinent provisions of 29 CFR 1902.3, 1902.4 and 1902.37, OSHA finds that the Nevada plan in actual operation provides for standards adoption, correction when found deficient, interpretation and application, in a manner at least as effective as the Federal Program.
(2) Variances. A State plan is expected to have the authority and procedures for the granting of variances comparable to those in the Federal program (29 CFR 1902.4(b)(2)(iv)). The Nevada State plan contains such provisions in both law and regulations which have been previously approved by OSHA. In order to qualify for final State plan approval, permanent variances granted must assure employment equally as safe and healthful as would be provided by compliance with the standard (29 CFR 1902.37(b)(6)); temporary variances granted must assure compliance as early as possible and provide appropriate interim employee protection (29 CFR 1902.37(b)(7)). As noted in the 18(e) Evaluation Report and the November 16 notice, Nevada had five requests for permanent variances during the 18(e) evaluation period. Two requests were approved, two were denied, and one was canceled. The granted variances were processed in accordance with State procedures. During the section 18(e) evaluation period, no temporary variance requests were received.

Accordingly, OSHA finds that the Nevada program is able to effectively grant variances from its occupational safety and health standards.

(3) Enforcement. Section 18(c)(2) of the Act and 29 CFR 1902.3(d)(1) require a State program to provide a program for enforcement of State standards which is and will continue to be at least as effective in providing safe and healthful employment and places of employment as those of Federal OSHA. OSHA concludes that Nevada’s enforcement program is comparable to those in the Federal Act. Nevada has procedures similar to Federal OSHA for processing and responding to complaints and for employee participation in State inspections. The data indicate that during the evaluation period the State was timely in responding to employee complaints, providing for employee participation in State inspections. The Act by such means as the posting of notices (29 CFR 1902.4(c)(2)(iv)), and provide that employees have access to information on their exposure to regulated agents and to records of the monitoring of their exposure to such agents (29 CFR 1902.4(c)(vi)).

To inform employees and employers of their protections and obligations, Nevada requires that a poster approved by OSHA be displayed in all covered workplaces. Requirements for the posting of the poster and other notices such as citations, contests, hearings and variances applications are set forth in the previously approved State law and regulations which are substantially identical to Federal requirements. Information on employee exposure to regulated agents and access to medical and monitoring records is provided through State standards which are identical to the Federal. No problems have been noted regarding notice of these actions to employers and employees. Therefore, OSHA has concluded that the State’s performance in this area is effective.

(c) Nondiscrimination. A State is expected to provide appropriate protection to employees against discharge or discrimination for exercising their rights under the State’s program including provision for employer sanctions and employee confidentiality (29 CFR 1902.4(c)(2)(v)). Section 618.445 of the Nevada Occupational Safety and Health Act and State regulations provide for discrimination protection equivalent to that provided by Federal OSHA. A total of 136 investigations of complaints alleging discrimination were completed during the evaluation period, of which 14 were found to be meritorious. The State takes appropriate action in the courts on merit cases where the employer does not voluntarily comply with the State’s proposed remedy. During the evaluation period, Nevada experienced difficulty in meeting the 90-day time limit for completion of discrimination investigations. The State took action to ensure timely processing of discrimination complaints, and State performance in this area is effective.

(3) Enforcement. Section 18(c)(2) of the Act and 29 CFR 1902.3(d)(1) require a State program to provide a program for enforcement of State standards which is and will continue to be at least as effective as the Federal program (29 CFR 1902.4(b)(2)(iv)). Nevada’s program is able to effectively grant variances from its occupational safety and health standards.

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(29 CFR 1902.4(c)(2)(vii)) and to provide adequate safeguards for the protection of trade secrets (29 CFR 1902.4(c)(2)(viii)). The State has provisions concerning imminent danger and protection of trade secrets in its law, regulations and operations manual which are similar to the Federal requirements. In addition, the Administrator of the Division of Industrial Relations may issue an emergency order to restrain an imminent danger situation. There were no imminent danger situations identified during the evaluation period. There were no Complaints About State Program Administration (CASPA’s) filed concerning the protection of trade secrets during the report period.

(e) Right of Entry; Advance Notice. A State program is expected to have authority for right of entry to inspect and compel managers to enforce such right equivalent to the Federal program (section 18(c)(3) of the Act and 29 CFR 1902.3(e)). In addition, a State is expected to prohibit advance notice of inspection, allowing exceptions there to no broader than the Federal program (29 CFR 1902.3(f)). Section 618.325 of the Nevada Occupational Safety and Health Act provides for an inspector’s right to enter and inspect all covered workplaces in terms substantially identical to those in the Federal Act. The Nevada law also prohibits advance notice, and implementing procedures for exceptions to this prohibition are substantially identical to the Federal procedures.

In order to be found qualified for final approval, a State is expected to take action to enforce its right of entry when denied (29 CFR 1902.37(b)(9)) and to adhere to its advance notice procedures. During the evaluation period, there were 14 denials of entry. Entry was achieved in 11 of these cases. This exceeds the Federal experience during the period. During the evaluation period, no advance notice of inspections was given.

(f) Citations, Penalties, and Abatement. A State plan is expected to have authority and procedures for promptly notifying employers and employees of violations identified during inspections, for the purpose of effective first-instance sanctions against employers found in violation of standards and for prompt employer notification of such penalties (29 CFR 1902.4(c)(2) (x) and (xi)). The Nevada plan, through its law, regulations and operations manual has established a system similar to the Federal program to provide for the prompt issuance of citations to employers delineating violations and establishing reasonable abatement periods, requiring posting of such citations for employee information, and proposing penalties.

In order to be qualified for final approval, the State, in actual operation, must be found to conduct competent inspections in accordance with approved procedures and to obtain adequate information to support resulting citations (29 CFR 1902.37(b)(10)), to issue citations, proposed penalties and failure-to-abate notifications in a timely manner (29 CFR 1902.37(b)(11)), to propose penalties for first-instance violations that are at least as effective as those under the Federal program (29 CFR 1902.37(b)(12)), and to ensure abatement of hazards including issuance of failure-to-abate notices and appropriate penalties (29 CFR 1902.37(b)(13)).

Procedures for the Nevada occupational safety and health compliance program are set out in the Nevada Operations Manual, which is patterned after the Federal manual. The State follows these procedures, including documentation procedures, which are similar to the Federal procedures. The 18(e) Evaluation Report notes overall adherence by Nevada to these procedures. In addition to issuing citations, the State issues “Notices of Violation” for other-than-serious violations that do not carry a penalty, when the employer agrees to abate the violation and not to contest. Nevada cited an average of 2.7 violations per safety inspection and 3.3 violations per health inspection; and 27% of both safety and health violations were cited as serious. The percentage of serious safety and health violations were lower than the comparable Federal percentages. While OSHA has disagreed with the State on the classification of some violations in the past, no systemic problems relating to violation classification have been found. The State continues to provide compliance officers with specific training and direction to ensure the proper classification of violations of standards. Nevada’s lapse time from the opening conference to issuance of citation averaged 40 days for safety and 53 days for health. Both of the lapse times are comparable to Federal OSHA’s citation lapse times.

Nevada’s procedures for calculation of penalties are similar to those of Federal OSHA. The 18(e) Evaluation Report noted that Nevada proposed higher penalties for serious violations than Federal OSHA. The average penalty for serious safety violations was $1844 and the average serious health penalty was $1336. Eighty-eight percent (88%) of serious safety violations had abatement periods of less than 30 days, and 97% of serious health violations had abatement periods of less than 60 days. This compares favorably to Federal performance. The Notice of Violation policy has been successful in assuring prompt abatement of other-than-serious violations without litigation.

(g) Contested Cases. In order to be considered for initial approval and certification, a State plan must have authority and procedures for employer contest of citations, penalties and abatement requirements at full administrative or judicial hearings. Employees must also have the right to contest abatement periods and the opportunity to participate as parties in all proceedings resulting from an employer’s contest (29 CFR 1902.4(c)(2)(xii)). Nevada’s procedures for employer and employee contest of citations, penalties and abatement requirements and for ensuring employees’ rights are contained in the law, regulations and operations manual made a part of the record in this proceeding. The Nevada plan provides for the review of contested cases by the Occupational Safety and Health Review Board, an independent administrative board. Decisions of the Review Board may be appealed to the appropriate State District Court.

Whenever appropriate, the State must seek administrative and judicial review of adverse adjudications. Additionally, the State must take necessary and appropriate action to correct any deficiencies in its program which may be caused by an administrative or judicial determination. See §§ 1902.37(b)(14) and 1902.3 (d) and (g). Nevada has taken action when appropriate to appeal adverse decisions. The Nevada 18(e) Evaluation Report noted that a case involving egregious citations was appealed to the Nevada Supreme Court by the State. The case was settled before hearing.

(h) Enforcement Conclusion. In summary, the Assistant Secretary finds that enforcement operations provided under the Nevada plan are competently planned and conducted, and are overall at least as effective as Federal OSHA enforcement.

(4) Public Employee Program: Section 18(c)(6) of the Act requires that a State which has an approved plan must maintain an effective and comprehensive safety and health program applicable to all employees of public agencies of the State and its political subdivisions, which program must be as effective as the standards contained in any approved plan. 29 CFR 1902.3(j) requires that a State’s program for public employees be as effective as
the State’s program for private employees covered by the plan. The Nevada plan provides a program in the public sector which is comparable to that in the private sector, including assessment of penalties for serious violations. Injury and illness rates in the public sector are comparable to private sector rates.

During the 18(e) Evaluation period, the State conducted 4.4% of its total inspections in the public sector. The results of these inspections were comparable to those in the private sector. Because Nevada’s performance in the public sector is comparable to that in the private sector, OSHA concludes that the Nevada program meets the criteria in 29 CFR 1902.3(j).

(5) Staffing and Resources. Section 18(c)(4) of the Act requires State plans to provide the qualified personnel necessary for the enforcement of standards. In accordance with 29 CFR 1902.37(b)(1), one factor which OSHA must consider in evaluating a plan for final approval is whether the State has a sufficient number of adequately trained and competent personnel to discharge its responsibilities under the plan.

The Nevada plan provides for 22 safety compliance officers and 9 industrial hygienists as set forth in the Nevada FY 1999 grant application. The FY 2000 grant application provides for 25 safety compliance officers and 12 industrial hygienists. This staffing level exceeds the revised “fully effective” benchmarks for Nevada for health and safety staffing of 11 safety and 5 health compliance officers approved by OSHA on September 11, 1987 [52 FR 34381]. At the close of the evaluation period the State had 20 safety and 9 health compliance officer positions filled.

Nevada utilizes the OSHA Training Institute for most of its staff training. The State also conducts internal training through staff meetings regarding any new issues or standards. In addition, enforcement and consultation staffs conduct joint regional meetings to discuss standards and other issues to ensure that enforcement and consultation have the same understanding of the requirements of the standards.

Because Nevada has allocated sufficient enforcement staff to meet the revised benchmarks for that State, and personnel are trained and competent, the requirements for final approval set forth in 29 CFR 1902.37(b)(1), and in the court order in AFL-CIO v. Marshall, supra, are being met by the Nevada plan.

Section 18(c)(5) of the Act requires that the State devote adequate funds to administration and enforcement of its standards. The Nevada plan was funded at $4,917,275 in FY 1999. ($1,163,000 (24%) of the funds were provided by Federal OSHA; Nevada matched this amount and contributed an additional $2,591,275 for a total State share of $3,754,275 (76%).)

As noted in the 18(e) Evaluation Report, Nevada’s funding exceeds Federal requirements in absolute terms; moreover, the State allocates its resources to the various aspects of the program in an effective manner. On this basis, OSHA finds that Nevada has provided sufficient funding and resources for the various activities carried out under the plan.

(6) Records and Reports: State plans must assure that employers in the State submit reports to the Secretary in the same manner as if the plan were not in effect (section 18(c)(7) of the Act and 29 CFR 1902.3(k)). The plan must also provide assurance that the designated agency will make such reports to the Secretary which form the “continuing participation” of such information as he may from time to time require (section 18(c)(8) of the Act and 29 CFR 1902.4(1)).

Nevada employer recordkeeping requirements are identical to those of Federal OSHA, and the State participates in the BLS Annual Survey of Occupational Injuries and Illnesses as well as the OSHA Data Initiative. The State participates and has assured its continuing participation with OSHA in the Integrated Management Information System (IMIS) as a means of providing reports on its activities to OSHA.

For the foregoing reasons, OSHA finds that Nevada has met the requirements of sections 18(c)(7) and (8) of the Act on employer and State reports to the Secretary.

(7) Voluntary Compliance: A State plan is required to undertake programs to encourage voluntary compliance by employers and employees (29 CFR 1902.4(c)(2)(iii)).

The Nevada consultation program, which until July 1, 1999 operated its private sector component under the State plan rather than OSHA’s section 21(d) consultation program, includes 14 consultants and 4 trainers. The State provides consultation services to both the private and public sectors. During the evaluation period, Nevada conducted 1781 consultation visits, primarily in smaller high hazard private sector establishments. From Fiscal Year 1996 through Fiscal Year 1999, the State conducted 739 safety and health classes, reaching a total of 6,737 employers and 8,551 employees. Training covered such issues as developing safety and health programs, lockout/tagout, fall protection, hazard communication and bloodborne pathogens. In addition, the Safety Consultation and Training Section has carried out substantial promotion and outreach efforts through a multi-media campaign, including television and newspaper public service announcements, funded by the State.

Accordingly, OSHA finds that Nevada has established and is administering an effective voluntary compliance program.

(8) Injury/Illness Rates: As a factor in its section 18(e) determination, OSHA must consider whether the Bureau of Labor Statistics’ annual occupational safety and health survey and other available Federal and State measurements of program impact on worker safety and health indicate that trends in worker safety and health injury and illness rates under the State program compare favorably with those under the Federal program. See § 1902.37(b)(15). Nevada’s lost workday case rate for private industry declined from 4.2 in 1994 to 3.3 in 1997. The lost workday case rate for construction decreased from 7.5 to 5.6, even though there was substantial growth in the construction industry particularly in the southern part of the State. The rate for manufacturing increased slightly from 5.0 to 5.2. The rate for State and local government decreased from 3.6 to 3.4.

OSHA finds that during the evaluation period trends in worker injury and illness in Nevada were comparable with those in States with Federal enforcement.

Decision

OSHA has carefully reviewed the record developed during the above described proceedings, including all comments received thereon. The present Federal Register document sets forth the findings and conclusions resulting from this review.

In light of all the facts presented on the record, the Assistant Secretary has determined that the Nevada State plan for occupational safety and health, which has been monitored for at least one year subsequent to certification, is in actual operation at least as effective as the Federal program and meets the statutory criteria for State plans in section 18(e) of the Act and implementing regulations at 29 CFR Part 1902. Accordingly, the Nevada State plan is hereby granted final approval under section 18(e) of the Act and implementing regulations at 29 CFR Part 1902, effective April 18, 2000.

Under this 18(e) determination, Nevada will be expected to maintain a State program which will continue to be at least as effective as operations under the Federal program in providing
employee safety and health at covered workplaces. This requirement includes submitting all required reports to the Assistant Secretary as well as submitting plan supplements documenting State-initiated program changes, changes required in response to adverse evaluation findings, and responses to mandatory Federal program changes. In addition, Nevada must continue to allocate sufficient safety and health enforcement staff to meet the benchmarks for State compliance staffing established by the Department of Labor, or any revision to those benchmarks.

**Effect of Decision**

The determination that the criteria set forth in section 18(c) of the Act and 29 CFR Part 1902 are being applied in actual operations under the Nevada plan terminates OSHA authority for Federal enforcement of its standards in Nevada, in accordance with section 18(e) of the Act. In those issues covered under the State plan, Section 18(e) provides that upon making this determination “the provisions of sections 5(a)(2), 8 (except for the purpose of carrying out subsection (f) of this section), 9, 10, 13, and 17, shall not apply with respect to any occupational safety and health issues covered under the plan, but the Secretary may retain jurisdiction under the above provisions in any proceeding commenced under section 9 or 10 before the date of determination.”

Accordingly, Federal authority to issue citations for violation of OSHA standards (sections 5(a)(2) and 9); to conduct inspections (except those necessary to conduct evaluations of the plan under section 18(f), and other inspections, investigations or proceedings necessary to carry out Federal responsibilities which are not specifically preempted by section 18(e) (section 8); to conduct enforcement proceedings in contested cases (section 10); to institute proceedings to correct imminent dangers (section 13); and to propose civil penalties or initiate criminal proceedings for violations of the Federal OSH Act (section 17) is relinquished as of the effective date of this determination.

Federal authority under provisions of the Act not listed in section 18(e) is unaffected by this determination. Thus, for example, the Assistant Secretary retains his authority under section 11(c) of the Act with regard to complaints alleging discrimination against employees because of the exercise of any right afforded to the employee by the Act, although complaints may be initially referred to the State for investigation. Any proceeding initiated by OSHA under sections 9 and 10 of the Act prior to the date of this final determination would remain under Federal jurisdiction. The Assistant Secretary also retains his authority under section 6 of the Act to promulgate, modify or revoke occupational safety and health standards which address the working conditions of all employees, including those in States which have received an affirmative 18(e) determination. In the event that a State’s 18(e) status is subsequently withdrawn and Federal authority reinstated, all Federal standards, including any standards promulgated or modified during the 18(e) period, would be Federally enforceable in the State.

In accordance with section 18(e), this determination relinquishes Federal OSHA authority only with regard to occupational safety and health issues covered by the Nevada plan, and OSHA retains full authority over issues which are not subject to State enforcement under the plan. Thus, for example, Federal OSHA retains its authority to enforce all provisions of the Act, and all Federal standards, rules or orders which relate to safety or health coverage of any private sector maritime activities (occupational safety and health standards comparable to 29 CFR Parts 1915, shipyard employment; 1917, marine terminals; 1918, longshoring; and 1919, gear certification, as well as provisions of general industry and construction standards (29 CFR Parts 1910 and 1926) appropriate to hazards found in the engagements, private employment on Indian land and any contractors or subcontractors on any Federal establishment where the land is exclusive Federal jurisdiction. Federal OSHA will also retain authority for coverage of the United States Postal Service (USPS), including USPS employees, contract employees, and contractor-operated facilities engaged in USPS mail operations and all Federal employers in Nevada. In addition Federal OSHA may subsequently initiate the exercise of jurisdiction over any issue (based on industry, geographical area, operation or facility) for which the State is unable to provide effective coverage for reasons which OSHA determines are not related to the required performance or structure of the State plan.

As provided by section 18(f) of the Act, the Assistant Secretary will continue to evaluate the manner in which the State is carrying out its plan. Section 18(f) and regulations at 29 CFR Part 1952 provide procedures for the withdrawal of Federal approval should the Assistant Secretary find that the State has subsequently failed to comply with any provision or assurance contained in the plan. Additionally, the Assistant Secretary is required to initiate proceedings to revoke an 18(e) determination and reinstate concurrent Federal authority under procedures set forth in 29 CFR 1902.47, et seq., if his evaluations show that the State has substantially failed to maintain a program which is at least as effective as operations under the Federal program, or if the State does not submit program change supplements to the Assistant Secretary as required by 29 CFR Part 1953.

**Explanation of Changes to 29 CFR Part 1952**

29 CFR Part 1952 contains, for each State having an approved plan, a Subpart generally describing the plan and setting forth the Federal approval status of the plan. 29 CFR 1902.43(a)(3) requires that notices of affirmative 18(e) determinations be accompanied by changes to Part 1952 reflecting the final approval decision. This notice makes changes to Subpart W of Part 1952 to reflect the final approval of the Nevada plan.

The table of contents for Part 1952, Subpart W, has been revised to reflect the following changes:

A new Section 1952.294, Final approval determination, which formerly was reserved, has been added to reflect the determination granting final approval of the plan. This section contains a more accurate description of the current scope of the plan than the one contained in the initial approval decision.

Section 1952.295, Level of Federal enforcement, has been revised to reflect the State’s 18(e) status. This replaces the former description of the relationship of State and Federal enforcement under an Operational Status Agreement voluntarily suspending Federal enforcement authority, which was entered into on December 9, 1981. Section 1952.295 describes the issues over which Federal authority has been terminated and the issues for which it has been retained in accordance with the discussion of the effects of the 18(e) determination set forth earlier in the present Federal Register notice.

Section 1952.296, Where the plan may be inspected, has been revised to reflect a new address for the Nevada Division of Industrial Relations.

**Regulatory Flexibility Act**

OSHA certifies pursuant to the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.) that this determination will not have a
significant economic impact on a substantial number of small entities. Final approval would not place small employers in Nevada under any new or different requirements, nor would any additional burden be placed upon the State government beyond the responsibilities already assumed as part of the approved plan.

Federalism

Executive Order 13132, “Federalism,” emphasizes consultation between Federal agencies and the States and establishes specific review procedures the Federal government must follow as it carries out policies which affect state or local governments. OSHA has included in the Background section of today’s final approval decision a detailed explanation of the relationship between Federal OSHA and the State plan States under the Occupational Safety and Health Act. OSHA has consulted extensively with Nevada throughout the period of 18(e) evaluation. Although OSHA has determined that the requirements and consultation procedures provided in Executive Order 13132 are not applicable to final approval decisions under the OSH Act, which have no effect outside the particular State receiving the approval, OSHA has reviewed the Nevada final approval decision proposed today, and believes it is consistent with the principles and criteria set forth in the Executive Order.

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health. It is issued under Section 18 of the OSH Act, (29 U.S.C. 667), 29 CFR Part 1902, and Secretary of Labor’s Order No. 1–90 (55 FR 9033).

List of Subjects in 29 CFR Part 1952

Intergovernmental relations, Law enforcement, Occupational safety and health, Reporting and recordkeeping requirements.

Signed at Washington, DC, this 6th day of April 2000.

Charles N. Jeffress,
Assistant Secretary.

Part 1952 of 29 CFR is hereby amended as follows:

PART 1952—[AMENDED]

1. The authority citation for part 1952 continues to read as follows:


Subpart W—Nevada

2. A new § 1952.294 is added, and §§ 1952.295 and 1952.296 are revised to read as follows:

§ 1952.294 Final approval determination.

(a) In accordance with section 18(e) of the Act and procedures in 29 CFR Part 1902, and after determination that the State met the “fully effective” compliance staffing benchmarks as revised in 1986 in response to a court order in AFL-CIO v. Marshall, 570 F.2d 1030 (D.C. Cir 1978), and was satisfactorily providing reports to OSHA through participation in the Federal-State Integrated Management Information System, the Assistant Secretary evaluated actual operations under the Nevada State plan for a period of at least one year following certification of completion of developmental steps. Based on an 18(e) Evaluation Report covering the period July 1, 1995 through March 31, 1999, and after opportunity for public comment, the Assistant Secretary determined that in operation the State of Nevada’s occupational safety and health program is at least as effective as the Federal program in providing safe and healthful employment and places of employment and meets the criteria for final State plan approval in section 18(e) of the Act and implementing regulations at 29 CFR Part 1902. Accordingly, the Nevada plan was granted final approval and concurrent Federal enforcement authority was relinquished under section 18(e) of the Act effective April 18, 2000.

(b) Except as otherwise noted, the plan which has received final approval covers all activities of employers and all places of employment in Nevada. The plan does not cover Federal government employers and employees; any private sector maritime activities; employment on Indian land; any contractors or subcontractors on any Federal establishment where the land is exclusive Federal jurisdiction; and the United States Postal Service (USPS), including USPS employees, contract employees, and contractor-operated facilities engaged in USPS mail operations.

(c) Nevada is required to maintain a State program which is at least as effective as operations under the Federal program; to submit plan supplements in accordance with 29 CFR Part 1953; to allocate sufficient safety and health enforcement staff to meet the benchmarks for State staffing established by OSHA, U.S. Department of Labor, or any revisions to those benchmarks; and, to furnish such reports in such form as the Assistant Secretary may from time to time require.

§ 1952.295 Level of Federal enforcement.

(a) As a result of the Assistant Secretary’s determination granting final approval to the Nevada State plan under section 18(e) of the Act, effective April 18, 2000, occupational safety and health standards which have been promulgated under section 6 of the Act do not apply with respect to issues covered under the Nevada Plan. This determination also relinquishes concurrent Federal OSHA authority to issue citations for violations of such standards under section 5(a)(2) and 9 of the Act; to conduct inspections and investigations under section 8 (except those necessary to conduct evaluation of the plan under section 18(f)) and other inspections, investigations, or proceedings necessary to carry out Federal responsibilities not specifically preempted by section 18(e); to conduct enforcement proceedings in contested cases under section 10; to institute proceedings to correct imminent dangers under section 13; and to propose civil penalties or initiate criminal proceedings for violations of the Federal OSH Act under section 17. The Assistant Secretary retains jurisdiction under the above provisions in any proceeding commenced under section 9 or 10 before the effective date of the 18(e) determination.

(b)(1) In accordance with section 18(e), final approval relinquishes Federal OSHA authority only with regard to occupational safety and health issues covered by the Nevada plan. OSHA retains full authority over issues which are not subject to State enforcement under the plan. Thus, Federal OSHA retains its authority relative to safety and health in private sector maritime activities and will continue to enforce all provisions of the Act, rules or orders, and all Federal standards, current or future, specifically directed to any private sector maritime activities (occupational safety and health standards comparable to 29 CFR Parts 1915, shipyard employment; 1917, marine terminals; 1918, longshoring; and 1919, gear certification, as well as provisions of general industry and construction standards (29 CFR Parts 1910 and 1926) appropriate to hazards found in these employments), employment on Indian land, and any contractors or subcontractors on any Federal establishment where the land is exclusive Federal jurisdiction. Federal jurisdiction is also retained with respect to Federal government employers and employees. Federal OSHA will also retain authority for coverage of the United States Postal Service (USPS),
including USPS employees, contract employees, and contractor-operated facilities engaged in USPS mail operations.

(2) In addition, any hazard, industry, geographical area, operation or facility over which the State is unable to effectively exercise jurisdiction for reasons which OSHA determines are not related to the required performance or structure of the plan shall be deemed to be an issue not covered by the State plan which has received final approval, and shall be subject to Federal enforcement. Where enforcement jurisdiction is shared between Federal and State authorities for a particular area, project, or facility, in the interest of administrative practicability Federal jurisdiction may be assumed over the entire project or facility. In any of the aforementioned circumstances, Federal enforcement authority may be exercised after consultation with the State designated agency.

(c) Federal authority under provisions of the Act not listed in section 18(e) is unaffected by final approval of the Nevada State plan. Thus, for example, the Assistant Secretary retains his authority under section 11(c) of the Act with regard to complaints alleging discrimination against employees because of the exercise of any right afforded to the employee by the Act, although such complaints may be referred to the State for investigation. The Assistant Secretary also retains his authority under section 6 of the Act to promulgate, modify or revoke occupational safety and health standards which address the working conditions of all employees, including those in States which have received an affirmative determination, although such standards may not be Federally applied. In the event that the State’s 18(e) status is subsequently withdrawn and Federal authority reinstated, all Federal standards, including any standards promulgated or modified during the 18(e) period, would be Federally enforceable in that State.

(d) As required by section 18(f) of the Act, OSHA will continue to monitor the operations of the Nevada State program to assure that the provisions of the State plan are substantially complied with and that the program remains at least as effective as the Federal program. Failure by the State to comply with its obligations may result in the suspension or revocation of the final approval determination under Section 18(e), resumption of Federal enforcement, and/or proceedings for withdrawal of plan approval.

§ 1952.296 Where the plan may be inspected.

A copy of the principal documents comprising the plan may be inspected and copied during normal business hours at the following locations: Office of State Programs, Directorate of Federal-State Operations, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N3700, Washington, DC 20210; Office of the Regional Administrator, Occupational Safety and Health Administration, Room 415, 71 Stevenson Street, San Francisco, California 94105; Office of the State Designee, Administrator, Nevada Division of Industrial Relations, 400 West King Street, Suite 400, Carson City, Nevada 89703.

[FR Doc. 00–9297 Filed 4–17–00; 8:45 am]
BILLING CODE 4510–26–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–00–121]

RIN 2115–AE47

Drawbridge Operation Regulations: Harlem River, Newtown Creek, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of three New York City Bridges; the Third Avenue Bridge, mile 1.9, across the Harlem River between Manhattan and the Bronx, the Madison Avenue Bridge, mile 2.3, across the Harlem River between Manhattan and the Bronx, and the Pulaski Bridge, mile 0.6, across the Newstown Creek between Brooklyn and Queens. This temporary final rule authorizes the bridge owner to close the above bridges on May 7, 2000, at different times of short duration to facilitate the running of the Five Boro Bike Tour. Vessels that pass under the bridges without a bridge opening may do so at any time.

DATES: This temporary final rule is effective from 8 a.m. until 12 p.m. on Sunday, May 7, 2000.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–00–121) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 6:30 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John W. McDonald, Project Officer, First Coast Guard District, (617) 223–8364.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553) to forego notice and comment for this rulemaking because notice and comment are impracticable. The Coast Guard believes notice and comment are impracticable because the requested closures are of such short duration. In the last two years, there have been few requests to open these bridges on Sundays during the hours they will be closed. Vessel traffic on the Harlem River and Newstown Creek is mostly commercial vessels that normally pass under the draws without openings. The commercial vessels that do require openings are work barges that do not operate on Sundays. The Coast Guard, for the reasons just stated, has also determined that good cause exists for this rule to be effective less than 30 days after it is published in the Federal Register.

Background

Third Avenue Bridge. The Third Avenue Bridge, mile 1.9, across the Harlem River between Manhattan and the Bronx, has a vertical clearance of 25 feet at mean high water and 30 feet at mean low water in the closed position. The existing operating regulations listed at § 117.789(c) require the draw to open on signal from 10 a.m. to 5 p.m., if at least a four-hour notice is given to the New York City Highway Radio (Hotline) Room. From 5 p.m. to 10 a.m., the draw need not be opened for vessel traffic.

Madison Avenue Bridge. The Madison Avenue Bridge, mile 2.3, across the Harlem River between Manhattan and the Bronx, has a vertical clearance of 25 feet at mean high water and 29 feet at mean low water in the closed position. The existing operating regulations listed at § 117.789(c) require the draw to open on signal from 10 a.m. to 5 p.m., if at least a four-hour notice is given to the New York City Highway Radio (Hotline) Room. From 5 p.m. to 10 a.m., the draw need not be opened for vessel traffic.

Pulaski Bridge. The Pulaski Bridge, mile 0.6, across the Newstown Creek between Brooklyn and Queens, has a vertical clearance of 39 feet at mean high water and 43 feet at mean low water in the closed position. The existing operating regulations require the draw to open on signal at all times.