The Bureau of Veterinary Medicine (BVM) concludes that the NADA contains human safety studies demonstrating that consumers will be protected with regard to possible residues remaining in the edible tissues of treated animals. Human investigation has demonstrated that norgestomet has no antiovulatory effects when administered orally up to 1.0 milligram per day. Based on rat (two-generation) and rhesus monkey reproduction studies, a hormonal no-effect level (using a 1000-fold safety margin) for humans has been calculated for norgestomet at 0.1 part per billion that coincides with the level to which the drug has been projected to deplete in all edible tissue within the 42-day (two attempted inseminations) inherent withdrawal period. Standards prescribed in the agency's proposal of March 20, 1979 (44 FR 17070) on chemical compounds in food-producing animals were not applied to the approval of norgestomet in this NADA. The approval is based on alternative criteria which assure that the product is safe and on factors which justify the equitable treatment of this sponsor who completed drug development testing adequately according to scientific standards extant before March 20, 1979.

The NADA also demonstrates that serum levels of estradiol–17 *beta* (estradiol valerate is exclusively transformed to this compound and its metabolities) essentially return to preinjection levels 9 days after treatment with estradiol valerate. BVM estimates that under foreseeable conditions of use, a withdrawal period of at least 51 days (9 days preceding implant removal plus 42 days inherent withdrawal) exists from time of administration of estradiol valerate until the earliest time of slaughter.

Because of the expected residue levels, the endogenous nature of estradiol–17 *beta*, and the inherent withdrawal period, BVM concludes that for this approval, post-slaughter regulatory methods of analysis for residues of norgestomet and estradiol valerate are not required by section 512(b)(7) of the act (21 U.S.C. 360b (b)(7)). Moreover, tolerances and withdrawal period are not required by section 512(b)(8) of the act. The inherent withdrawal period is reasonably certain to be followed in practice. Based on the foregoing, the NADA is approved, and the regulations are amended to reflect the approval.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The Bureau's finding of no significant impact and the evidence supporting this finding, contained in a statement of exemption (pursuant to 21 CFR 25.1(f)(1)(ii)(*e*)(*3*)) may be seen in the Dockets Management Branch (address above).

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 522

Animal drugs, Injectable.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended by adding new § 522.850, to read as follows:

§ 522.850 Estradiol valerate and norgestomet in combination.

(a) *Specifications.* The product is a two-component drug consisting of the following:

(1) An implant containing 6.0 milligrams of norgestomet.

(2) An injectable solution (sesame oil) containing 3.0 milligrams of norgestomet and 5.0 milligrams of estradiol valerate per 2 milliliters.

(b) *Sponsor.* See 000014 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One implant and 2 milliliters of injection at time of implantation.

(2) *Indications for use.* For synchronization of estrus/ovulation in cycling heifers.

(3) *Limitations.* Insert implant subcutaneously in the ear only; then immediately inject solution intramuscularly only. Counting the day of implantation as day 1, remove the implant on day 10. Collect all implants as they are removed and burn them. While animals are restrained for artificial insemination, avoid other treatments such as vaccinations, dipping, pour-on grub and louse prevention, spraying, etc. When inseminating without estrus detection, the entire treated group should be started at 48 hours after the last implant has been removed and should be completed within 6 hours. Where estrus detection is preferred, insemination should be approximately 12 hours after first detection of estrus. Those that do not conceive can be re-bred when they return to estrus approximately 17 to 25 days after implant removal. Do not use in cows producing milk for human consumption.

Effective date. This regulation is effective December 10, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: December 3, 1982.

Lester M. Crawford,

Director Bureau of Veterinary Medicine.

[FR Doc. 82–33664 Filed 12–9–82; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7843]

Indirect Foreign Tax Credit for Domestic Corporations Required To Include Amounts in Gross Income With Respect to Certain Third-Tier Corporations Under Section 951

Correction

In FR Doc. 82–30416 beginning on page 50471 in the issue of Monday, November 8, 1982, make the following corrections:

1. In § 1.960–1(c)(3), in the 22nd line from the top of the third column of page 50473, the text belonging in paragraph (ii) should end with the words "are attributable", and the text beginning with "then, for the purposes * * *" should begin a new line.

2. In § 1.960–1(h)(1)(ii), in the 27th line from the top of the third column of page 50475, the text belonging to paragraph (ii) should end with "960(a)(1),", and the text beginning with "shall be deemed * * *" should begin a new line.

3. In § 1.960–2(e)(2), in the fourth line from the bottom of the third column, the text belonging to paragraph (2) should end with the words "of this section," and the text beginning with the words "then, for purposes * * *" should begin a new line.

4. In § 1.960–2(f), Example 8, in the 13th line from the bottom of the third column, the citation "§ 1.960–2(b)(2) (i)

and (ii)" should have read "§ 1.960–2(d)(2) (i) and (ii)".

BILLING CODE 1505-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1903

Use of Personal Sampling Devices During Inspection

AGENCY: Occupational Safety and Health Administration (OSHA); Department of Labor.

ACTION: Final rule.

SUMMARY: This document amends 29 CFR 1903.7 to expressly authorize compliance officers to use personal sampling devices and to attach such devices to employees during the conduct of workplace inspections. This amendment is necessitated by conflicting judicial decisions as to whether the present regulation provides sufficient authorization for OSHA to use personal sampling devices.

EFFECTIVE DATE: January 10, 1983.

FOR FURTHER INFORMATION CONTACT: Mr. James Foster, Office of Public Affairs, Occupational Safety and Health Administration, Third Street and Constitution Avenue, N.W., Room N3641, Washington, D.C. 20210 (202–523–8151).

SUPPLEMENTARY INFORMATION

I. Background

On February 12, 1982, the Occupational Safety and Health Administration ("OSHA" and the "agency") published two documents in the **Federal Register**: (1) An interpretative and procedural rule which clarified the term "reasonable investigative techniques" as used in 29 CFR 1903.7(b), and (2) a notice of proposed rulemaking which proposed to amend § 1903.7(b) to expressly authorize OSHA compliance officers to use personal sampling devices and to attach such devices to employees during the conduct of workplace inspections (47 FR 6530–34). The agency invited the public to submit written data, views and arguments with respect to the proposed amendment and all issues involved therein, particularly with respect to whether the placement of a sampling device, e.g., noise dosimeter or air sampling pump, on an employee may under certain circumstances constitute an inherent hazard which subjects the employee to potential accident and injury. Comments were to be postmarked by April 13, 1982.

The agency has received forty-five comments from businesses, unions, trade associations, law firms and others. In addition, comments relating to the issues in this proceeding were submitted by OSHA field personnel. All submissions were made part of the record and were duly considered.

Three commentors requested public hearings on the proposed amendment. *See* Exhibits 2–23, 2–25, 2–27. The agency considered these requests and determined that public hearings would not be held. Since the regulation at 29 CFR 1903.7(b) is not an occupational safety and health standard as defined by Section 3(8) of the Occupational Safety and Health Act (the "Act"), 29 U.S.C. 652(8), the provisions of Section 6(b) of the Act, 29 U.S.C. 655(b), do not apply. Additionally, hearings are not required by the Administrative Procedure Act when, as here, an agency is engaged in informal rulemaking. 5 U.S.C. 553; *Vermont Yankee Nuclear Power Corp.* v. *National Resources Defense Council*, 435 U.S. 519 (1978). Furthermore, the commentors that requested the hearings did not claim any inability to present views through written submissions and a review of the comments received tended to reinforce the agency's belief that hearings would result only in the addition to the record of information which at most would duplicate or corroborate the written comments without providing further elucidation of the issues involved. Accordingly, the agency determined that public hearings, with their concomitant costs and delay, would not be held.

II. Statutory Framework

The Occupational Safety and Health Act of 1970 (the "Act"), 29 U.S.C. 651 *et seq.*, was enacted "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." In order to carry out these purposes, Section 8(a) of the Act, 29 U.S.C. 657(a), authorizes the Secretary of Labor ("Secretary"), upon presenting appropriate credentials to the owner, operator or agent in charge, to conduct workplace inspections and investigations. Pursuant to the rulemaking authority granted by Section 8(g)(2) of the Act, 29 U.S.C. 657(g)(2), the Secretary, in 1971, promulgated regulations designed "to provide procedures and policies for the inspection [and] investigation provisions of the Act." (36 FR 8376 *et seq.*). Included among these regulations was 29 CFR 1903.7, which authorized Compliance Officers "to take environmental samples" and "employ other reasonable investigative techniques" during the conduct of OSHA inspections.

Since the adoption of 29 CFR Part 1903, the Secretary has consistently and unambiguously interpreted § 1903.7 to allow and in fact encourage the use of personal sampling devices such as noise dosimeters and air sampling pumps and badges as aids in workplace inspections. The Secretary's Compliance Operations Manual, Field Operations Manual and Industrial Hygiene Field Operations Manual all reflect a longstanding belief that personal sampling generally provides the most accurate measure of an employee's exposure to noise or air contaminants. Consistent with this interpretation of § 1903.7 are the Secretary's policies and practices in monitoring employee exposures, as acknowledged by various administrative and court decisions. Additionally, the Secretary's experience during his years of enforcement activities establishes that the use of personal sampling devices is a safe and efficient method of monitoring employee exposure levels.

Notwithstanding the above, two courts issued decisions which adversely affected the agency's ability to conduct personal sampling. In *Plum Creek Lumber Co.* v. *Hutton*, 608 F.2d 1283 (9th Cir. 1979), the Ninth Circuit held that, absent a law or regulation specifying their use, a court could not order recision of a company policy prohibiting employees from wearing personal sampling devices. In *In re Establishment Inspection of Metro-East Mfg. Co.* and *In re Establishment Inspection of Century Casting Corp.*, 655 F.2d 805 (7th Cir. 1981), the Seventh Circuit concluded that the regulation at 29 CFR 1903.7 did not give employers "fair warning" of conduct required or prohibited since the regulation did not specify the use of personal sampling devices as a "reasonable investigative technique." Thus, although both courts concluded that the use of personal samplers is reasonable, the Secretary was unable to conduct personal sampling in either case. During the interim, the Eighth Circuit, *In re Establishment Inspection of Keokuk Steel Castings, Division of Kast Metals*, 638 F.2d 42 (1981) and several district courts declined to follow the *Plum Creek* decision and concluded that personal sampling is a reasonable technique which the Secretary may employ.

III. Summary of Proposed Amendments

On February 12, 1982, OSHA published in the **Federal Register** an interpretative and procedural rule

together with a notice of proposed rulemaking. The interpretative/procedural rule clarified the regulation at 29 CFR 1903.7 by adding an interpretative note that stated that the term "employ other reasonable investigative techniques" includes the attachment of personal sampling devices to employees in order to monitor their exposures (47 FR 6533). The notice of proposed rulemaking announced the agency's intention to issue a legislative rule expressly authorizing compliance officers to use personal sampling devices and to attach such devices to employees during OSHA inspections (47 FR 6534). The proposed revision would thus codify the February 12, 1982 interpretative/procedural rule.

As previously noted, the agency received forty-five public comments and numerous submissions from OSHA field personnel. Following is a discussion of the major comments received and the relevant issues raised therein.

Statutory Authority

Many commentors stated that the Act contains no statutory authority for the proposed rule. *See*, e.g., Exhibits 2–2, 2–13, 2–14, 2–18, 2–19, 2–29, 2–34, 2–40, 2–41, 2–44. Additionally, a recent U.S. District Court decision stated that there is no such authority. *Service Foundry Co. v. Donovan*, No. 82–3091 (E.D. La. August 27, 1982). The agency disagrees with this view. Sections 8(a) (1) and (2) authorize the Secretary, upon presentation of appropriate credentials, to enter any workplace and to inspect and investigate within reasonable limits and in a reasonable manner all conditions pertinent to the purposes of this Act. The exposure of employees to toxic substances or harmful physical agents is clearly a condition affecting employee safety and health. Thus, sections 8(a) (1) and (2) clearly authorize the Secretary to determine the identity of substances to which employees are exposed and the qualitative and quantitative nature of their exposure by any reasonable means, such as by the use of personal sampling devices. Furthermore, section 8(g)(2) of the Act, 29 U.S.C. 657(g)(2), authorizes the Secretary to "prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment." This provision, described by the Supreme Court as a grant of "broad authority" to the Secretary, *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307, 317 n.12 (1978), clearly authorizes rulemaking for the proposed personal sampler rule. Indeed, the Seventh Circuit suggested that the Secretary amend § 1903.7 to clarify its meaning. *In re Establishment Inspection of Metro-East Mfg. Co.*, 655 F.2d 805, 812 (1981). Thus, the Secretary plainly is empowered to adopt a rule which authorizes the use of personal sampling devices to monitor noise and air contaminants in a workplace.

Safety

In proposing the amendment to § 1903.7, the agency specifically invited public comment on the issue of whether the placement of the device on an employee may under certain circumstances constitute an inherent hazard which subjects the employee to potential accident and injury. In so doing, OSHA noted that all courts that have considered the issue have concluded that the attachment of a personal sampler to an employee is a reasonable investigative technique that presents minimal risk, if any. Furthermore, the Secretary stated that he was unaware of any accident or injury caused by the use of such devices during more than 10 years of OSHA enforcement activities, and that he considered the use of personal sampling to be at least as safe as alternate sampling techniques of equivalent efficiency.

The record amply corroborates the Secretary's experience. Although some commentors asserted that generally the use of personal samplers creates potential risks to employees, *see*, e.g., Exhibits 2–15, 2–30, 2–37, 2–44, none of these comments specifies any accident or injury caused by the use of such devices. Indeed, several commentors stated that they had no record or knowledge of any such accident or injury. *See* Exhibits 2–6, 2–7, 2–17, 2–38. Moreover, the submissions of OSHA field personnel, reflecting years of experience and thousands of inspections, reveal only one incident, which involved a spill from an impinger of approximately 5 ml of toluene reagent and resulted in a small degree of skin irritation. *See* Exhibits 3–19(1) and 3–19(21). These submissions otherwise state that the OSHA personnel have no record or knowledge of any accident or injury related to the use of personal samplers. Furthermore, the comments demonstrate that, in the professional opinion of the OSHA Industrial Hygienists, the use of personal sampling devices is the safest effective method of obtaining employee exposure data.

In addition to the above, the record establishes that the use of personal sampling devices is widespread among industry. OSHA field personnel submitted the names of hundreds of companies known to use the devices to monitor exposure levels. *See*, e.g., Exhibits 3–3, 3–4, 3–5, 3–6(1), 3–6(8), 3–6(11), 3–6(14), 3–6(27), 3–7(1), 3–9(6), 3–13(1), 3–18(2), 3–19(18), 3–20. Also identified were companies that either hire consultants or have insurance companies monitor exposure levels through the use of personal samplers. *See*, e.g., Exhibits 3–11(1), 3–15(3), 3–16(2), 3–18, 3–19(1). Several companies stated in their comments that they routinely use the devices, *see* Exhibits 2–7, 2–20, 2–43; other commentators stated that they support and agree with the agency's efforts to utilize personal samplers, *see* Exhibits 2–1, 2–6, 2–9, 2–11, 2–17, 2–20, 2–35.

Based on the foregoing, the agency finds that the use of personal sampling devices, widespread among industry, is, if not the safest, at least as safe as alternate sampling techniques of equivalent efficiency. Such alternate techniques, e.g., area sampling or having an OSHA compliance officer wear a sampler and follow the employee during a work shift, are almost uniformly described by OSHA Industrial Hygienists as less efficient, less accurate and more dangerous than using personal samplers attached to the employee whose exposure is being monitored. *See*, e.g., Exhibits 3–4, 3–5(2), 3–6(24), 3–11(2), 3–14, 3–19(21), 3–19(58). In addition, several comments were received from representatives of different types of industries and organizations which rely on the use of personal sampling devices to obtain employee exposure data. These commentors stated that this type of equipment is of paramount importance as the most effective means of determining exposure levels and producing statistically valid data while at the same time being the most accurate means available to measure employee exposure, *see* Exhibits 2–6, 2–7, 2–17, 2–20, 2–43. These devices have been found to be more effective than area sampling to monitor a worker's individual dose, and are a more efficient means of obtaining a sample than the cumbersome practice of following an employee around during the course of a workshift. In light of the general acceptance of the devices and the above-mentioned factors which contribute to the widespread use of personal samplers, the agency concludes that the authority to use personal sampling devices is necessary for the effective and efficient conduct of OSHA health inspections.

Finally, the need to use personal sampling devices is not obviated in those situations in which the employer has sampled its employees' exposure to

toxic substances or harmful physical agents in its workplace. The quantitative nature of worker exposure to toxic substances can vary greatly depending on a variety of factors which are present in the workplace. These variables include such factors as: the work process(es) undertaken by the employer and the enactment of any process changes which would result in different employee exposures; the work practices followed by individual employees; and, variations in workplace environmental conditions such as temperature and pressure fluctuations, along with ambient air flow changes resulting from seasonal variations, and the effectiveness of ventilation/engineering controls where relied upon to reduce employee exposures. Thus, an employer's samples may not be an accurate indication of employee exposure on any given day. Furthermore, without supervising the employer's sampling and the analysis of that sampling, OSHA has no way of determining the accuracy of an employer's samples, even if the employer is in good faith conducting sampling in a responsible and conscientious fashion. Since such results can be greatly affected by the procedures followed by the persons conducting the sampling and those analyzing the samples, OSHA believes it necessary to take its own samples to accurately determine employee exposure to toxic substances and harmful physical agents. Moreover, OSHA can not ignore the possibility that in rare instances, an employer's sampling may be performed or analyzed in a manner which may purposely understate employee exposure to harmful substances.

General Comments

Several commentors stated that employees who decline to wear personal samplers should not be compelled by OSHA to wear the devices. *See* Exhibits 2–9, 2–14, 2–16, 2–19, 2–29, 2–34, 2–35, 2–37, 2–38, 2–40, 2–41, 2–44. Initially, the agency notes that in its experience the overwhelming majority of employees readily agree to wear the sampling devices when asked. *See,* e.g., Exhibits 3–6(9), 3–6(25), 3–11(2), 3–13(2), 3–18, 3–19(1), 3–19(10). With respect to those who decline, it is neither agency practice nor policy to compel an employee to wear a personal sampling device. Rather, when faced with such a refusal, the agency attempts to ascertain and alleviate the employee's concern; if these efforts are unsuccessful, another employee is asked to wear the device.

Some commentors stated that the attachment of personal sampling devices to employees and the employees' wearing of the devices are disruptive and interfere with ongoing work. *See,* e.g. Exhibits 2–2, 2–16, 2–18, 2–32, 2–33, 2–39. OSHA has concluded that the interference with an employer's work operations inherent in the investigative and sampling process is generally minimal and that the interruptions occasioned by the use of personal samplers are no greater, and in many instances are less substantial, than with the use of the other sampling techniques. In addition, the agency has taken steps to keep such interruption to a minimum. For example, OSHA Industrial Hygienists usually discuss with the employer at the opening conference that fact that sampling will be conducted and oftentimes seek to arrange with the employer a convenient time to begin sampling. Additionally, the agency attempts whenever practicable to attach the sampling devices to employees before a work shift begins; subsequent calibration and spot checks are usually of short duration. Finally, the agency notes that § 1903.7 requires the sampling to be conducted so as to preclude unreasonable disruptions of the employer's operations. In view of the agency's own practices and the limitations contained in § 1903.7(d), it is unnecessary to add further restrictions regarding the conduct of personal sampling.

Many commentors were concerned that results obtained from personal sampling devices may be inaccruate. Some of these commentors stated that sampling devices are inherently inaccurate, *see,* e.g., Exhibits 2–15, 2–30, 2–33, or are subject to employee tampering, *see,* e.g., Exhibits 2–5, 2–21, 2–30, 2–37, 2–45. Other commentors noted that the regulation lacks specific guidelines regarding the placement of the device, calibration techniques and monitoring or spot checking. *See,* e.g., Exhibits 2–4, 2–8, 2–22. However, these comments raise issues more appropriately addressed in the context of an evidentiary hearing on the merits of a citation and the agency therefore declines to include such guidelines in the regulation itself.

Some commentors expressed the view that the use of personal sampling devices in a particular industry or under certain working conditions is inappropriate or dangerous. *See,* e.g., Exhibits 2–1, 2–12, 2–13, 2–23, 2–31, 2–42. The agency of course recongnizes that personal sampling is not appropriate in some instances and indeed OSHA Industrial Hygienists have refrained form using the devices when in their judgment circumstances require alternate sampling techniques. *See,* e.g., Exhibits 3–15(7), 3–19(1). However, the purpose of the instant rulemaking proceeding is not to establish personal sampling as the sole means of monitoring exposure levels; in fact, the regulation is not limited to personal sampling and includes authority to utilize other devices as well, such as area samplers. Rather than focusing on a particular method of sampling for use in all circumstances, this rulemaking is intended to codify the agency's general authority to use sampling devices to the extent judicial decisions have not already recognized this authority. The use of any device or sampling technique remains subject to the professional judgment of the agency's compliance personnel.

One commentor stated that § 1903.7 as written could be interpreted to authorize the performance of unlimited tests upon employees such as blood testing, urinalysis and skin-patch testing. *See* Exhibit 2–3. However, it is not the agency's intention to authorize such tests of an employee's body. Rather, the agency views the regulation at § 1903.7 as authorizing external monitoring of noise and air contaminants through the use, *inter alia,* of dosimeters and air sampling pumps. Any monitoring involving employees' body fluids or internal testing is beyond the scope of this rulemaking.

Regulatory Impact Analysis

In accordance with Executive Order 12291 (46 FR 13193, February 17, 1981), OSHA has carefully assessed the potential impact of the amendment to 29 CFR 1903.7(b). Based on the guidelines of the Executive Order, OSHA has concluded that the amendment is not a "major" action which would necessitate further economic impact evaluation and preparation of a regulatory impact analysis. This conclusion is predicated on several factors. First, it has always been the Secretary's practice to use personal sampling devices on employees whenever possible. The Secretary's experience and the record indicate that these devices are compact, take minimal time to attach to the employee, and neither hinder not obstruct in any significant way the employee's performance of his job. Thus, there are no tangible adverse labor productivity effects. Second, since OSHA is required to provide the personal samplers for use by its compliance officers, employers are not required to pay for these devices. Therefore, these factors strongly indicate that this amendment would have virtually no effect on costs

to employers and on the economy as a whole.

Additionally, in accordance with the Regulatory Flexibility Act of 1980 (Pub. L. 96–353, 94 Stat. 1164 (5 U.S.C. 601 et seq.)), OSHA has carefully assessed the impact of the amendment upon small entities. Initially, the agency notes that to the extent that any costs occur, they would directly relate to the number of workers sampled. Since proportionately the same number of workers would be sampled in both larger and smaller establishments, the costs of the amendment on each unit produced are expected to be relatively the same for both smaller and larger establishments. Moreover, no additional costs result from the amendment since it has always been and continues to be OSHA practice to use personal sampling devices whenever possible and whenever there is no judicial ruling to the contrary. Accordingly, OSHA hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities.

The Regulatory Impact Assessment has identified several benefits which are realized as a result of the promulgation of the amendment. As has been noted in connection with the interpretative and procedural rule, *see* 47 FR 6530 (Feb. 12, 1982), the use of personal sampling devices attached to employees not only increases the effectiveness of OSHA inspections but also minimizes potential reduction in employee productivity. The use of personal sampling devices attached to employees is therefore the most cost effective means of promoting occupational safety and health.

Authority: This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

List of Subjects in 29 CFR Part 1903

Law enforcement, Occupational safety and health, Health, Administrative practice and procedures.

PART 1903—INSPECTIONS, CITATIONS, AND PROPOSED PENALTIES

Accordingly, pursuant to section 8(a) and 8(g)(2) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 657(a) and 657(g)(2), and the Secretary of Labor's Order 8–76, 41 FR 25059, Part 1903 of Title 29 of the Code of Federal Regulations is amended by revising paragraph (b) of § 1903.7 as set forth below.

§ 1903.7 Conduct of inspections.

* * * * *

(b) Compliance Safety and Health Officers shall have authority to take environmental samples and to take or obtain photographs related to the purpose of the inspection, employ other reasonable investigative techniques, and question privately any employer, owner, operator, agent or employee of an establishment. (See § 1903.9 on trade secrets.) As used herein, the term "employ other reasonable investigative techniques" includes, but is not limited to, the use of devices to measure employee exposures and the attachment of personal sampling equipment such as dosimeters, pumps, badges and other similar devices to employees in order to monitor their exposures.

* * * * *

(29 U.S.C. 657(a), 657(g); 5 U.S.C. 553)

Signed at Washington, D.C., December 2, 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 82-33412 Filed 12-9-82; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 535

Iranian Assets Control Regulations; Judicial Action Involving Standby Letters of Credit

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Final rule.

SUMMARY: The Office of Foreign Assets Control is amending the Iranian Assets Control Regulations; (1) to clarify the provision in paragraph (b)(3) of § 535.504 revoking and withdrawing all prior general licenses which may have authorized final judicial action permanently disposing of Iranian interests in standby letters of credit or similar instruments; and (2) to extend for one year the expiration date of that paragraph. The purpose of this amendment is to make clear that the effect of such license revocation and withdrawal is that any such judgments or orders which were entered prior to July 2, 1982, but which had not become final by that date through the conclusion of appellate proceedings or the expiration of the time for appeal, are prohibited.

The extension for another year is needed to facilitate the ongoing implementation of the Iran-U.S. agreements of January 19, 1981 (the "Algiers Accords") and, especially, to allow the resolution before the Iran-U.S. Claims Tribunal of the many claims and issues pending before it, including jurisdictional questions, involving letters of credit.

EFFECTIVE DATE: December 7, 1982.

FOR FURTHER INFORMATION CONTACT: Raymond W. Konan, Chief Counsel, Office of Foreign Assets Control, Department of the Treasury, Washington, D.C., tel. (202) 376–0236.

SUPPLEMENTARY INFORMATION: Section 535.504(b)(3), which was added to the regulations in an amendment issued on July 1, filed with the **Federal Register** on July 2 and published in the **Federal Register** on July 7, 1982 (the "July 2 amendment"), clearly prohibits any final judicial judgment or order permanently disposing of any interest of Iran in any standby letter of credit or similar obligation. That amendment was intended to apply not only to future actions, but also to any judicial judgment or order which was entered before July 2, 1982, but which had not become final by that date through the conclusion of appellate proceedings or the expiration of the time for appeal. That intent was shown by the provision in the July 2 amendment revoking and withdrawing all prior licenses and the accompanying supplementary information which specifically provided that the purpose of the amendment was to "allow U.S. account parties to obtain preliminary injunctions or other temporary relief to prevent payment on standby letters of credit, while prohibiting, for the time being, final judicial action permanently enjoining, nullifying or otherwise permanently disposing of such letters of credit." However, because a question has arisen as to the intended application of the July 2 amendment, the present amendment expressly clarifies that any judgment or court order which finally extinguishes Iran's interest in a standby letter of credit or similar obligation is prohibited, including any such judgment or order which was entered prior to July 2, 1982, but which was subject to appellate proceedings as of that date, such as the judgment in the case of *Itek* v. *First National Bank of Boston*, U.S.D.C.D. Mass., C.A. No. 80–58–MA, appeal pending Nos. 82–1631, 82–1632, 82–1633. Section 535.402 does not negate the application of this amendment, or the prior amendment that it clarifies, to such judgments.

The reasons for section 535.504(b)(3) were set forth with the July 2 amendment. See 47 FR 29529. These reasons are still applicable and justify the one-year extension of § 535.504(b)(3) effected here.

Iran has filed with the Iran-United States Claims Tribunal 229 claims based on standby letters of credit or similar bank instruments. On December 1, 1982, the United States filed with the Tribunal a request that the Tribunal determine which, if any, of these claims come within the Tribunal's jurisdiction. On October 25, 1982, Iran filed with the Tribunal an allegation that the United States has violated its obligations under the Algiers Accords by failing to transfer to Iran the amounts of these standby letters of credit. The Tribunal may rule both on the United States jurisdictional request and on the Iranian allegation as to United States obligations under the Accords within the next year. The pendency of these proceedings before the Tribunal and the possibility of rulings on either or both issues make advisable the continuation of § 535.504(b)(3) for another year.

Since the Regulations involve a foreign affairs function, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation and delay in effective date, are inapplicable. Similarly, because the Regulations are issued with respect to a foreign affairs function of the United States, they are not subject to Executive Order 12291 of February 17, 1981, dealing with federal regulations. Since no notice of proposed rulemaking is required for this regulation, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., are not applicable to this regulation.

List of Subjects in 31 CFR Part 535

Iran, Foreign assets control.

PART 535—IRANIAN ASSETS CONTROL REGULATIONS

31 CFR Part 535 is amended as follows:

Section 535.504 is amended by revising (b)(3)(i) and (b)(3)(v) to read as follows:

§ 535.504 Certain judicial proceedings with respect to property of Iran or Iranian entities.

* * * * *

(b) This section does not authorize:

* * * * *

(3)(i) Any final judicial judgment or order (A) permanently enjoining, (B) terminating or nullifying, or (C) otherwise permanently disposing of any interest of Iran in any standby letter of credit, performance bond or similar obligation. Any license authorizing such action is hereby revoked and withdrawn. This revocation and withdrawal of prior licenses prohibits judgments or orders that are within the terms of this subparagraph (3)(i), including any such judgments or orders which may have been previously entered but which had not become final by July 2, 1982, through the conclusion of appellate proceedings or the expiration of the time for appeal.

* * * * *

(v) The provisions of this paragraph (b)(3) shall expire at 11:59 p.m., e.s.t., on December 31, 1983.

(Sec. 201–207, 91 Stat. 1626, 50 U.S.C. 1701–1706; E.O. No. 12170, 44 FR 65729; E.O. No. 12205, 45 FR 24099; E.O. No. 12211, 45 FR 26605; E.O. No. 12276, 46 FR 7913, E.O. No. 12278, 46 FR 7917, 46 FR 10695; E.O. No. 12279, 46 FR 7919; E.O. No. 12280, 46 FR 7921; E.O. No. 12281; 46 FR 7923; E.O. No. 12282, 46 FR 7926; and E.O. No. 12294, 46 FR 14111)

Dated: December 7, 1982.

Dennis M. O'Connell,

Director, Office of Foreign Assets Control.

Approved:

John M. Walker, Jr.,

Assistant Secretary, Enforcement and Operations.

[FR Doc. 82-33653 Filed 12-7-82; 4:11 pm]

BILLING CODE 4810-25-M

VETERANS ADMINISTRATION

38 CFR Part 17

Patients' Rights

AGENCY: Veterans Administration.

ACTION: Final rule.

SUMMARY: The Veterans Administration (VA) has amended its "Medical Series" of regulations concerning the "Protection of Patient Rights" to set forth, in part, specific minimum substantive and procedural rights to be uniformly afforded both involuntary and voluntary patients undergoing treatment in a VA medical center. Included are regulations which define and protect patients' rights in the areas of privacy, least restrictive treatment, exercise of legal rights, visitation, communication, restraint, seclusion, medication, dress, fund handling, general medical and psychiatric treatment, social interaction, exercise, and religion.

EFFECTIVE DATE: December 6, 1982.

FOR FURTHER INFORMATION CONTACT: D. C. Rasinski, M.D., J.D., Special Assistant to the Chief Medical Director for Professional Services, Department of Medicine and Surgery, Veterans Administration, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 389–2221.

SUPPLEMENTARY INFORMATION: The VA proceeded on two paths in the development of patients' rights regulations. One, set forth herein, concerned only patients' rights while the other, which is undergoing review, concerns rights of committed patients. The latter, when published, will both complement and complete the former. The final patients' rights regulations are being published at 38 CFR 17.34a. Section 17.34b thereof will be reserved for the regulations dealing with rights of committed patients.

Comments from seventeen persons and organizations were received concerning the proposed patients' rights regulations published on pages 3061–3063 of the **Federal Register** of January 16, 1980. Six comments addressed the issue of providing patients notice of their rights. A provision has been added requiring patients to be given notice of their rights upon admission.

Four comments were received concerning the nature of the privacy right to be afforded patients. The commentators suggested that the right to privacy should include confidentiality of patient records, privacy during treatment consistent with VA resources (including bathing and dressing by staff members of the same sex), smoke-free rooms, adequate private storage space and a further discussion of how the right to privacy will be maintained.

It is believed that existing law adequately addresses patient record confidentiality in statutes set forth at section 552a of title 5, United States Code and sections 3301 and 4132 of title 38, United States Code.

The VA has long advocated patient privacy during treatment in its Code of Patient Concern which provides that "[c]ase discussion, consultation, examination, and treatment are confidential and should be conducted discreetly."

While the VA attempts to provide, upon patient request, a staff member of the same sex to bathe or dress the patient, the VA is unable to assure such a right because its patient population is predominantly male while its Nursing Service staff is predominantly female.

The VA, through local medical center management policies, balances the competing interests of smokers and nonsmokers by generally prohibiting smoking in the rooms of acute patients, providing day rooms or smoking lounges for smokers and by placing ambulatory nonsmoking patients in rooms with other nonsmoking patients whenever possible. In addition, each medical center has been directed to carry out an ongoing education program for patients and staff on the hazards of smoking.

The VA strives to meet patient privacy standards set by the Joint

Commission on Accreditation of Hospitals. New medical centers are designed with patients' rooms accommodating one, two or four persons, while existing facilities, as modernized, are partitioned to meet the same standards. Each patient is furnished a bedside cabinet consisting of a drawer and shelf space and locker/wardrobe containing a shelf, clothing rod, drawer and cylinder lock. In addition, centralized storage space for luggage or other possessions of the patient is furnished.

The right to privacy afforded under this regulation is intended to afford patients maximum privacy consistent with VA resources. It is believed better to broadly define the right while providing a patient complaint and review procedure in commitment and patients' rights regulations to be promulgated rather than to attempt to detail every aspect of patient privacy by regulation.

Seven comments were addressed to the proposed regulation concerning patient visitation and communication. Three commentators believed that standards for imposing restrictions on visitation or communication were not specific enough, thereby affording the medical staff too much discretion.

Two commentators suggested that reasons for any restrictions should be entered in the patients' medical record. Other specific suggestions or criticisms included the following: Patients should have notice of and consent to restrictions in a judicial forum; patients should have unrestricted access to mail; patients' rights concerning visitation and communication should only be restricted where patients or others would suffer actual harm; privacy of communications with courts and a doctor of the patient's choice are not sufficiently protected; the patient's attorney is afforded no right to visit; restrictions should not be based on the fact that communications contain obscenities or prejudice the public credibility of the patient; absolute visitation rights should include recognized veterans' representatives; and disclosure of threats of future crime should be limited to either those involving physical violence to persons or property or disclosures specifically authorized by State and Federal statutes.

The final regulation balances the patient's freedom to visit and communicate with the need for medical staff professional judgment and discretion to restrict those rights only when necessary for the protection of the patient or others, or for the operation of the medical facility. Additional objective criteria have been provided as a necessary precondition to any restriction together with requirements for documenting the reasons for any restrictions imposed and notifying the patient of those restrictions. The final regulation responds to concerns expressed about the extent of the discretion afforded staff and the vagueness of the standards to be applied in assuring that the rights of patients are safeguarded.

While the final regulation does not provide specific judicial review rights, it is not intended to be in derogation of any such rights which a patient may have under applicable law. The final regulation does not incorporate a concept analogous to "actual harm" as a necessary component of the standard for imposing restrictions while rejecting the concept of a patient's absolute right to have unrestricted access to mail. It also continues to protect the absolute right to communicate with attorneys, law enforcement agencies or Government officials (which is intended to encompass courts) but does not make that right absolute in the case of private physicians of the patient's choice. Adequate procedural safeguards are provided involuntary patients to guard against the provision of improper medical treatment. In addition, the wide use of specialized consultation services within VA medical centers as well as the prevalent use of private attending and consulting physicians assures the patient of the availability, when necessary, of a second opinion. The voluntary patient has the additional option of seeking alternative care.

The final regulation retains the absolute right of the patient to be visited by his or her attorney. However, the right is one to be exercised by the patient rather than the attorney. The right to visitation by recognized service organization representatives is made absolute in those cases where the representative is acting as the veteran's agent in a matter concerning VA benefits.

The final regulation does not base restriction of communications on a standard relating to obscenity or protection of public credibility of the patient per se, however, depending on the specific set of facts, such concerns could be considered in applying a "valid and sufficient reason" standard. This is a stricter standard than that identified in the proposed regulation. The final regulation leaves unchanged the proposed regulation provision concerning confidentiality of information obtained from patient mail except for disclosure of threats of future crime to law enforcement authorities. The provision is not intended to mandate disclosure to law enforcement authorities but to authorize disclosure if a qualified health professional determines that the threat is real and that the patient has the means and ability to carry it out.

Ten commentators provided suggestions or criticism of the subsection of the proposed regulation concerning restraint and seclusion. Eight were concerned with the frequency of monitoring by both professional and other ward personnel.

Two commentators suggested that psychologists as well as physicians should be able to order restraint or seclusion. Five commentators expressed concern about whether the standard set forth for imposing restraint or seclusion was specific enough. One commentator suggested that the authority of the personnel monitoring the restraint or seclusion to terminate it when it is no longer necessary be set forth in the regulation and that patients in restraint be assured of motion and exercise for at least ten minutes every two hours except at night. One commentator suggested that a physician's order should always be necessary for the imposition of restraint or seclusion and that these measures only be used on an emergency basis. One commentator suggested that chemical restraints be included in the regulation.

The final regulation sets forth a stricter standard for imposing restraints or seclusion. It discards the proposed regulation standard of a reasonable anticipation that the patients could harm themselves or others in favor of a "substantial risk of imminent harm by the patient to himself, herself, or others" standard. Monitoring by ward personnel pursuant to the final regulation is required at least hourly. While an appropriate health professional is only required to see a patient in restraint or seclusion every twelve hours, that limitation is not intended to set the standard of practice but only the outside boundary for such monitoring. It is expected that ordinarily such patients will be seen more frequently.

The final regulation continues to repose authority to impose restraint or seclusion with physicians rather than psychologists. Frequently, the disruptive behavior which necessitates restraint or seclusion is based on medical factors such as a metabolic disturbance, and epileptic seizure prodrome or a drug reaction. Often such a patient requires examination for injuries producing pain. It is believed that such restrictions should, therefore, only be imposed on a physician's order.

It is unnecessary to indicate in the regulation that professional personnel monitoring patients have the authority to terminate restraint or seclusion when no longer required. Physicians clearly have that authority while other ward personnel ought not to have that independent authority. Sound medical practice would dictate that the responsible physician be notified if ward personnel believe that restraint or seclusion is no longer justified. Similarly, the right of the patient to have motion or exercise is properly a matter for professional judgment depending on the severity of the condition which necessitated the imposition of restraint, and should be restricted only in the most unusual clinical situation.

It is the intent of the final regulation to require a physician's order to impose restraints on a patient except in very limited circumstances for a very limited time when common sense would dictate that the patient or others must be immediately protected. The regulation, however, provides for prompt contact with a physician when such emergency restraint or seclusion is used.

Six commentators offered their views concerning provisions of the proposed regulation concerning medication. Two commentators expressed concern about emergency administration of medication by nonphysicians and one commentator wished to expand the category of personnel who are given authority to prescribe and review medication to include other health care professionals. The VA believes that only physicians should ordinarily prescribe medication but allowance must be made for a true emergency situation where time does not permit contact with a physician. Such situations are expected to be rare and it is the intent of the final regulation that personnel other than physicians not administer medication except in a bona fide emergency. Two commentators suggested more frequent review of a patient's drug regimen. The final regulation retains the 30 day review standard which is believed to be a reasonable maximum review period standard and is not intended to set a standard of practice for review.

Four commentators provided their views regarding that part of the proposed regulations dealing with patients' dress and money. One noted that since VA issues fire retardant pajamas, patients who elect to wear their own should be required, for their protection, to wear fire retardant pajamas. Two commentators discussed the standard for restriction of clothing or personal possessions. One thought the standard should relate to immediate dangerousness and that if a restriction were to be imposed because of inappropriateness it should be made part of the patient's treatment plan and the patient should have the right to contest it. The other thought that only a standard relating to dangerousness was appropriate and that the decision to restrict should be reviewed at least weekly. One commentator thought the standard for restricting patient and fund handling was vague and another thought that funds should only be restricted when the patient was adjudicated incompetent by a court or when a Federal agency was designated a payee for monetary benefits.

The final regulation has been revised to employ the stricter "valid and sufficient reason" standard for restrictions regarding patients' clothing or possessions. This is the same standard used regarding allowable restrictions on visitation and communication. This standard could authorize a requirement that patients, for their protection, wear fire retardant pajamas. The final regulation also mandates review of such restrictions at least once every thirty (30) days.

The final regulations refer to instructions published by the Department of Medicine and Surgery, Veterans Administration, concerning personal funds of patients. These instructions, recently revised, provide extensive detailed guidelines for handling patients' funds. Patients' accounts can be restricted under these guidelines if: (1) The patient is adjudged incompetent by a court; (2) the patient has been rated incompetent by the VA; (3) the patient is a psychiatric patient and a competency rating is pending; or (4) patients are considered by their treatment team to be incapable of handling their own funds. Patients are provided notice of appeal rights and a specific appeal procedure which assures due process. These guidelines specifically prohibit restriction of patients' accounts for punitive reasons or as a means of modifying patient behavior. Review of restrictions is required when the patient's condition warrants a change or at least every 6 months.

Four commentators addressed the provisions of the proposed rule dealing with the right to general medical treatment. One commentator suggested subsuming that right under the general rights described in paragraph (a), and including the right to prompt and appropriate health care for any physical, emotional or behavioral problem. One commentator questioned whether medical management includes treatment and suggested adding a requirement for a full physical examination upon admission. Another commentator thought that the term "medical management" was too vague and thought the right should include a doctor's prompt attention and treatment. Another commentator thought the right should include prompt life-saving treatment in an emergency without discrimination.

The proposed regulation arose out of traditional concern for the physical well-being of patients. The VA has always offered its patients prompt and appropriate care for any condition for which a patient was legally eligible for treatment including psychiatric care and life-saving treatment in an emergency. The use of the term "management" in the proposed regulation was intended to be broader than, and to encompass, treatment. Medical management includes the services of the entire health care them.

The final regulation has been modified to reflect that VA patients have a right to receive prompt and appropriate medical and/or psychiatric treatment for any physical or emotional ailment for which the patient is eligible by law. We intend for the term treatment to have the broad meaning mentioned above.

Three commentators provided their views concerning the portion of the proposed regulation dealing with rights of patients to social interaction. Two were concerned that the standard used for imposing restrictions, i.e., "detrimental to the welfare of the patient or others," was too vague or too broad. One commentator thought the standard should be actual harm to the patient or others and should be supported by documentation together with weekly review of any restriction. One commentator noted that the regulation did not discuss notice to the patient or the right to protest.

The final regulation adopts the "valid and sufficient reason" standard which is also employed as a standard for restricting visitation, communication, dress or use of personal possessions. It provides notice of the restrictions to the patient, prohibits misuse of such restriction and requires periodic review of such restrictions.

Five commentators submitted comments about the right to exercise set forth in the proposed rule. Three expressed concern over the standard used for imposing restrictions. One commentator thought exercise should only be restricted when it threatened actual medical harm to the patient and that this should be supported by documentation and the restriction

discontinued when no longer necessary. One commentator asked what enivronmental considerations would override the right to exercise. One believed that the right to exercise should include physical and other therapies when requested, ordered by a health professional and approved by a physician. One commetator was concerned that the proposed regulation would be interpreted to mean that only gymnasium-type equipment was appropriate.

The reference to environmental considerations in the proposed regulation related to a right to be outdoors frequently rather than to exercise. The final regulation, however, has been revised to eliminate overriding medical or environmental considerations per se as standards by which restrictions could be imposed. The final regulation adopts the "valid and sufficient reason" standard which is consistent with the standard adopted with regard to most of the other patients' rights afforded by this regulation. It is intended that medical center management determine what equipment and facilities could be useful to promote patient exercise. Gymnasium-type facilities or equipment are not specifically required. Physical and other therapies need not be specifically mentioned with regard to the right to exercise. Such therapies are continually offered as needed and are encompassed in the patient's right to medical management for any physical ailment.

Five commentators remarked on the provisions of the proposed regulation concerning the right of religious worship. One commentator believed that the right to religious worship should be absolute and never be abridged. Two commentators questioned whether the right to religious worship could be restricted without raising serious constitutional questions. One commentator thought the regulation should contain an affirmative duty to provide religious services for all patients regardless of religion or location. One commentator was concerned that the proposed regulation would affirmatively require the VA to provide religious services for specific denominations or religions. One commentator was concerned about notice to the patient of restrictions and the right to contest such restrictions.

The VA has long had a Chaplain Service in recognition of the positive role that a religious ministry can play in the total care and treatment of hospital patients. The VA is also firmly committed to recognizing patients' basic right to religious worship. The right to religious worship, however, is not absolute and considerations of health and safety can impinge on it. The final regulation has been revised to adopt the "valid and sufficient reason" standard for placing any restriction on a patient's right to worship. It also imposes the additional safeguards of notice to the patient, the requirement for a written entry in the patient's treatment plan, a written order by a health professional in the patient's medical record, periodic review of applicability of restrictions and a prohibition against misuse of such restrictions. The final regulation is intended to allow the patient to worship as he or she pleases provided no valid and sufficient reason warrants a restriction of such right, but the regulation does not require that any particular kind of religious service be provided or that such services must be provided at any particular place. The VA will continue its practice of making as widely available as possible opportunities for religious worship. The Chaplain Service encourages its chaplains to work with the management of medical centers to make such opportunities available, consistent with available resources, to all patients irrespective of physical condition or location.

Five commentators offered miscellaneous recommendations concerning matters which do not appear to be specifically covered in the proposed regulation. These include the following recommendations or criticisms: No prohibition against corporal punishment; no provision for automatic expiration after three days of restrictions imposed by a physician for psychiatric treatment reasons; no affirmative statement that patients are presumed to be legally competent and have first amendment rights of self-organization and assembly; failure to make any restriction of rights the sole responsibility of the treating physician or medical director; freedom from unnecessary or excessive procedures including surgery, radiation and invasive clinical laboratory tests; a right to have the name and specialty of the attending physician; right to have patient advocates; right to have unannounced checks on medical centers by impartial observers; and assurance of protection for VA employees from discrimination or imposition of penalties for reporting violations of patients' rights, questionable medical treatment or inadequate living conditions.

Existing VA regulations, set forth at 38 CFR 0.735–20(e)(5) (1979), specifically prohibit employees from abusing patients, including physical and verbal abuse.

It is believed preferable to approach monitoring any restriction of patients' rights which might be imposed for a valid and sufficient reason by means of reference to change in the patient's condition while setting mandatory parameters for review to prevent undue restrictions. When a restriction is imposed for a valid and sufficient reason it does not appear prudent to cause a presumably necessary restriction to automatically lapse, so long as there is provision for regular, systematic review of the restrictions and the reasons therefor.

The regulation identifies four bases, each of which may constitute a "valid and sufficient reason" in an individual case for the imposition of a restriction on certain patient rights. Such a valid and sufficient reason for restricting full exercise of a specific right may exist when a health or mental health professional reasonably believes that unfettered exercise of the right would:

(1) Adversely affect the patient's physical or mental health;

(2) Be likely to stigmatize the patient's reputation to a degree that would adversely affect a return to independent living;

(3) Significantly infringe on the rights of or jeopardize the health or safety of others; or

(4) Have a significant adverse impact on the operation of the medical facility.

It is not intended, however, that all four of the grounds for a restriction be considered to be available with respect to each of the rights involved. For example, the protection of the patient from stigmatization that would adversely affect the patient's return to independent living would not logically be related to the right to physical exercise nor would the protection of the operation of a medical facility warrant a restriction on the patient's rights to convenient and reasonable opportunities for communication by telephone and sealed mail. Thus, it is intended that the health or mental health professional considering imposition of a restriction determine that a clear and logical relationship exists between the right involved and the basis for the restriction and that the seriousness and likelihood of the specified consequences expected to result from the patient's exercise of the right involved are so compelling as to outweigh the patient's interest in exercising that right.

The final regulation clearly indicates that upon admission to a VA medical center patients retain all legal rights not

circumscribed by law. The specific examples given of the rights retained—right to execute legal instruments, right to enter into contractual relationships, right to register and vote and others—quite clearly support the conclusion that such patients are presumed competent particularly when such rights, by the terms of the final regulation, cannot be limited except when the patient is adjudicated incompetent by a court. It appears unnecessary to further define that presumption or to reiterate verbatim patients' first amendment rights.

The final regulation generally permits restrictions supported by a valid and sufficient reason to be imposed by an appropriate health professional except in specific areas such as restraint, seclusion and medication, where the focus is on the responsibility of a physician. It is believed that, while the physician bears ultimate responsibility for the care and treatment of his or her patients, appropriately trained health professionals under the direction of a physician can and should participate in many aspects of the care and treatment of patients including, where necessary, restriction of their activity.

The extent to which a patient requires surgery, radiation or invasive diagnostic tests is one peculiarly within a physician's judgment—while the ultimate decision is clearly that of the patient. By statute 38 U.S.C. 4131 (1976), and implementing regulations, (codified at 38 CFR 17.34) patients are guaranteed that all treatment, to the maximum extent practicable, is carried out only with the full and informed consent of the patient or, in appropriate cases, the patient's representative. In addition, Chapter 23 of the Department of Medicine and Surgery Manual M–2, Part 1 fully explains the VA policy on informed consent. An open and honest dialogue between physician and patient coupled with the patient's ultimate right to decide whether to undergo surgery, radiation or invasive diagnostic tests provides appropriate protection for the patient.

Congress has not specifically authorized the expenditure of patient care funds to implement a patient advocate program throughout the VA health care system. Some VA medical centers, however, through the use of social workers or other qualified personnel, provide patient relations services. The VA is reviewing and evaluating the effect of these services on patient care. Legislation has been introduced to provide for patient advocacy programs. In view of these conditions and developments, the VA will defer instituting any systemwide patient advocacy program at this time.

The VA has a variety of audit, review, and quality assurance mechanisms, both internal and external, under the jurisdiction of the Health Services Review Organization, to assure the proper operation of VA health care facilities and the optimum level of care for the patients the VA serves. It would be unnecessary, duplicative and inappropriate to add another regulatory review requirement in these patients' rights regulations.

Federal employees are already afforded so-called "whistle blower" protection under provisions of the Civil Service Reform Act of 1978, set forth at 5 U.S.C. 2302(b)(8), which prohibits certain personnel practices as a reprisal for reasonably disclosing violations of law, rule or regulation, abuse of authority, or a substantial and specific danger to public health or safety. In addition, the Inspector General of the VA maintains a toll-free telephone line on which anyone including employees, may report, anonymously if desired, fraud or abuse. These mechanisms provide adequate assurance that employees will be protected if they report violations of patients' rights.

The Administrator has determined that these regulations are non-major as that term is defined by Executive Order 12291. The regulations will only apply to patients and staff in VA hospitals, nursing homes and domiciliaries. Accordingly, the regulation will not result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or (3) significant adverse effects on competition, employment investment, productivity, innovation, or on the ability of United States-based enterprise to compete with foreign-based enterprises in domestic or export markets.

The Administrator hereby certifies that these regulations will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), these regulations are therefore exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604. The reason for this certification is that this rule will, almost exclusively, be directed to the provision of care by VA staff in VA facilities. It will, therefore, have no significant impact on small entities (i.e., small business, small private and non-profit organizations, and small governmental jurisdictions.)

Catalog of Federal Domestic Assistance Numbers: 64.001 through 64.022.

List of Subjects in 38 CFR Part 17

Health care, Health facilities, Mental health programs, Health professions, Nursing homes, Veterans.

Approved: December 6, 1982.

By direction of the Administrator.

Everett Alvarez, Jr.,

Deputy Administrator.

PART 17—MEDICAL

Section 17.34a is added to read as follows:

§ 17.34a Patients' rights.

(a) *General.* (1) Patients have a right to be treated with dignity in a humane environment that affords them both reasonable protection from harm and appropriate privacy with regard to their personal needs.

(2) Patients have a right to receive, to the extent of eligibility therefor under the law, prompt and appropriate treatment for any physical or emotional disability.

(3) Patients have the right to the least restrictive conditions necessary to achieve treatment purposes.

(4) No patient in the Veterans Administration medical care system, except as otherwise provided by the applicable State law, shall be denied legal rights solely by virtue of being voluntarily admitted or involuntarily committed. Such legal rights include, but are not limited to, the following:

(i) The right to hold and to dispose of property except as may be limited in accordance with paragraph (c)(2) of this section;

(ii) The right to execute legal instruments (e.g., will);

(iii) The right to enter into contractual relationships;

(iv) The right to register and vote;

(v) The right to marry and to obtain a separation, divorce, or annulment;

(vi) The right to hold a professional, occupational, or vehicle operator's license.

(b) *Residents and inpatients.* Subject to paragraph (c) of this section, patients admitted on a residential or inpatient care basis to the Veterans Administration medical care system have the following rights:

(1) *Visitations and communications.* Each patient has the right to communicate freely and privately with persons outside the facility, including government officials, attorneys, and

clergymen. To facilitate these communications each patient shall be provided the opportunity to meet with visitors during regularly scheduled visiting hours, convenient and reasonable access to public telephones for making and receiving phone calls, and the opportunity to send and receive unopened mail.

(i) Communications with attorneys, law enforcement agencies, or government officials and representatives of recognized service organizations when the latter are acting as agents for the patient in a matter concerning Veterans Administration benfits, shall not be reviewed.

(ii) A patient may refuse visitors.

(iii) If a patient's right to receive unopened mail is restricted pursuant to paragraph (c) of this section, the patient shall be required to open the sealed mail while in the presence of an appropriate person for the sole purpose of ascertaining whether the mail contains contraband material, i.e., implements which pose significant risk of bodily harm to the patient or others or any drugs or medication. Any such material will be held for the patient or disposed of in accordance with instructions concerning patients' mail published by the Department of medicine and Surgery, Veterans Administration, and/or the local health care facility.

(iv) Each patient shall be afforded the opportunity to purchase, at the patient's expense, letter writing material including stamps. In the event a patient needs assistance in purchasing writing material, or in writing, reading or sending mail, the medical facility will attempt, at the patient's request, to provide such assistance by means of volunteers, sufficient to mail at least one (1) letter each week.

(v) All information gained by staff personnel of a medical facility during the course of assisting a patient in writing, reading, or sending mail is to be kept strictly confidential except for any disclosure required by law.

(2) *Clothing.* Each patient has the right to wear his or her own clothing.

(3) *Personal Possessions.* Each patient has the right to keep and use his or her own personal possessions consistent with available space, governing fire safety regulations, restrictions on noise, and restrictions on possession of contraband material, drugs and medications.

(4) *Money.* Each patient has the right to keep and spend his or her own money and to have access to funds in his or her account in accordance with instructions concerning personal funds of patients published by the Department of Medicine and Surgery.

(5) *Social Interaction.* Each patient has the right to social interaction with others.

(6) *Exercise.* Each patient has the right to regular physical exercise and to be outdoors at regular and frequent intervals. Facilities and equipment for such exercise shall be provided.

(7) *Worship.* The opportunity for religious worship shall be made available to each patient who desires such opportunity. No patient will be coerced into engaging in any religious activities against his or her desires.

(c) *Restrictions.* (1) A right set forth in paragraph (b) of this section may be restricted within the patient's treatment plan by written order signed by the appropriate health or mental health professional if—

(i) It is determined pursuant to paragraph (c)(2) of this section that a valid and sufficient reason exists for a restriction, and

(ii) The order imposing the restriction and a progress note detaining the indications therefor are both entered into the patient's permanent medical record.

(2) For the purpose of this paragraph, a valid and sufficient reason exists when, after consideration of pertinent facts, including the patient's history, current condition and prognosis, a health or mental health professional reasonably believes that the full exercise of the specific right would—

(i) Adversely affect the patient's physical or mental health,

(ii) Under prevailing community standards, likely stigmatize the patient's reputation to a degree that would adversely affect the patient's return to independent living,

(iii) Significantly infringe upon the rights of or jeopardize the health or safety of others, or

(iv) Have a significant adverse impact on the operation of the medical facility, to such an extent that the patient's exercise of the specific right should be restricted. In determining whether a patient's specific right should be restricted, the health or mental health professional concerned must determine that the likelihood and seriousness of the consequences that are expected to result from the full exercise of the right are so compelling as to warrant the restriction. The Chief of Service or Chief of Staff, as designated by local policy, should concur with the decision to impose such restriction. In this connection, it should be noted that there is no intention to imply that each of the reasons specified in paragraphs (c)(2) (i) through (iv) of this section are logically relevant to each of the rights set forth in paragraph (b)(1) of this section.

(3) If it has been determined under paragraph (c)(2) of this section that a valid and sufficient reason exists for restricting any of the patient's rights set forth in paragraph (c)(1) of this section, the least restrictive method for protecting the interest or interests specified in paragraphs (c)(2) (i) through (iv) of this section that are involved shall be employed.

(4) The patient must be promptly notified of any restriction imposed pursuant to this paragraph and the reasons therefor.

(5) All restricting orders must be reviewed at least once every 30 days by the practitioner and must be concurred in by the Chief of Service or Chief of Staff.

(d) *Restraint and seclusion of patients.* (1) Each patient has the right to be free from physical restraint or seclusion except in situations in which there is a substantial risk of imminent harm by the patient to himself, herself, or others and less restrictive means of preventing such harm have been determined to be inappropriate or insufficient. Patients will be physically restrained or placed in seclusion only on the written order of a physician. The reason for any restraint order will be clearly documented in the progress notes of the patient's medical record. The written order may be entered on the basis of telephonic authority received from a physician, but in such an event the ordering physician must examine the patient and sign the written order within twelve (12) hours of giving the order for restraint or seclusion. In emergency situations, where inability to contact a physician prior to restraint is likely to result in immediate harm to the patient or others, the patient may be temporarily restrained by a member of the staff until appropriate authorization can be received from a physician. Use of restraints or seclusion shall be for no more than twenty-four (24) hours, at which time the physician shall again be consulted to determine if continuance of such restraint or seclusion is required. Restraint or seclusion may not be used as a punishment, for the convenience of staff, or as a substitute for treatment programs.

(2) While in restraint or seclusion, the patient must be seen at least once every twelve (12) hours by an appropriate health professional who will monitor and chart the patient's physical and mental condition and by other ward personnel as frequently as is reasonable under existing circumstances, but no less than once each hour.

(3) Each patient in restraint or seclusion shall have bathroom privileges according to his or her needs.

(4) Each patient in restraint or seclusion shall have the opportunity to bathe at least every twenty-four (24) hours.

(5) Each patient in restraint or seclusion shall be provided nutrition and fluid appropriately.

(e) *Medication.* Patients have a right to be free from unnecessary or excessive medication. Except in an emergency, medication will be administered only on the written order of a physician in that patient's medical record. The written order may be entered on the basis of telephonic authority received from a physician, but in such event a physician must countersign the written order within 24 hours of the ordering of the medication. The attending physician shall be responsible for all medication given or administered to a patient. The attending physician shall review the drug regimen of each patient under his or her care at least every thirty (30) days. It is recognized that administration of certain medications will be reviewed more frequently. Medication shall not be used as punishment, for the convenience of the staff, or in quantities which interfere with the patient's treatment program.

(f) *Confidentiality.* Information gained by staff from the patient or the patient's medical record will be kept confidential and will not be disclosed except in accordance with applicable law.

(g) *Patient grievances.* Each patient has the right to present grievances with respect to perceived infringement of the rights described in this section or concerning any other matter on behalf of himself, herself or others, to staff members at the facility in which the patient is receiving care, other Veterans Administration officials, government officials, members of Congress or any other person without fear or reprisal.

(h) *Notice of patient's rights.* Upon the admission of any patient, the patient or his/her representative shall be informed of the rights described in this section, shall be given a copy of a statement of those rights and shall be informed of the fact that the statement of rights is posted at each nursing station. All staff members assigned to work with patients will be given a copy of the statement of rights and these rights will be discussed with them by their immediate supervisor.

(i) *Other rights.* The rights described in this section are in addition to and not in derogation of any statutory, constitutional or other legal rights. (38 U.S.C. 210, 621)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[SWH-FRL 2263-8]

National Oil and Hazardous Substances Contingency Plan

AGENCY: Environmental Protection Agency.

ACTION: Notice of Effective Date.

SUMMARY: On July 16, 1982, pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 and Executive Order 12316, the Environmental Protection Agency promulgated revisions to the National Oil and Hazardous Substances Contingency Plan. The regulation was transmitted to Congress for review, as required by section 305 of CERCLA. During the period for congressional review, neither House disapproved the regulation. The revised Plan, therefore, shall be effective as of December 10, 1982.

EFFECTIVE DATE: December 10, 1982.

FOR FURTHER INFORMATION CONTACT: Sylvia Lowrance, Office of Emergency and Remedial Response (WH-548), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, Phone (202) 382-2203.

SUPPLEMENTARY INFORMATION: Pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Pub. L. 96-510 ("CERCLA" or "the Act") and Executive Order 12316, the Environmental Protection Agency ("EPA" or "the Agency"), promulgated revisions to the National Oil and Hazardous Substances Contingency Plan ("NCP") on July 16, 1982. (See 47 FR 31180). EPA explained that the revisions could not become effective until the period for congressional review had passed. That period has passed and, by this notice, the Agency is establishing the effective date for the revised NCP to be the date of publication of this notice.

The revised NCP implements the new responsibilities and powers created by CERCLA. CERCLA provides that actions taken in response to releases of hazardous substances shall, to the greatest extent possible, be in accordance with the revised NCP. Section 311 of the Clean Water Act provides that actions taken to remove oil discharges shall, to the greatest extent possible, be in accordance with the NCP. The revised NCP is applicable to response actions taken pursuant to CERCLA and section 311 of the Clean Water Act.

Section 305(a) of CERCLA provides that the promulgation of a regulation under authority of Title I of CERCLA is subject to congressional review. Section 305(b) provides that a regulation may become effective at the end of 60 calendar days of continuous session of Congress after the date of promulgation if "no committee of either House of Congress has reported or been discharged from further consideration of a concurrent resolution disapproving the rule or regulation and neither House has adopted such a resolution." The congressional review period has expired. Congress took no action on the revised NCP during the review period. Therefore, the revised NCP shall become effective on December 10, 1982.

Dated: December 3, 1982.

Rita M. Lavelle,

Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 82-33675 Filed 12-9-82; 8:45 am]
BILLING CODE 6560-50-M

MARINE MAMMAL COMMISSION

50 CFR Part 540

National Security Information

AGENCY: Marine Mammal Commission.

ACTION: Final rule.

SUMMARY: The Marine Mammal Commission is revising its regulation establishing agency national security information policy. This revision amends the current Part 540 so as to conform it to the provisions of Executive Order 12356, National Security Information, as they apply to the Commission.

DATE: Effective January 10, 1983.

ADDRESS: Marine Mammal Commission, Washington, D.C. 20006.

FOR FURTHER INFORMATION CONTACT: John R. Twiss, Jr., Executive Director, Marine Mammal Commission, 1625 I Street, NW., Room 307, Washington, D.C. 20006; (202) 653-6237.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 26, 1979 (44 FR 55381-55382), the MMC published its final rule implementing the