the Executive Order. In addition, the philosophy and principles identified in impacts; and equity). The agency and other advantages; distributive environmental, public health and safety, (including potential economic, necessary, to select regulatory alternatives and, when regulation is directed by therule the requirements of premarket approval, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IX. Comments

Interested persons may, on or before January 2, 1996 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individual may submit one copy. Comments are to be identified with the name of the device and the docket number found in brackets in the heading of this document. Received comments may be seen in theoffice above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subject in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:


2. New § 888.3070 is added to subpart D to read as follows:

   § 888.3070 Pedicle screw spinal system.

   (a) Identification. A pedicle screw spinal system is a multiple component device, made of alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, unalloyed titanium, and Ti-6Al-4V, that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of anchors (e.g., bolts, hooks, and screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and plate/rod combinations); and transverse connectors. The device is intended to provide immobilization and stabilization of spinal segments in the treatment of significant medical instability or deformity requiring fusion with instrumentation including significant medical instability secondary to spondylolisthesis, vertebral fractures, and dislocations, scoliosis, kyphosis, spinal tumors, and pseudarthrosis resulting from unsuccessful fusion attempts.

   (b) Classification. Class II (special controls).
Register, the Bureau provides a description of the “Access Control Entry/Exit System, JUSTICE/BOP-010.”

This Order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612, this order will not have a significant economic impact on a substantial number of small entities.

**List of Subjects in Part 16**


Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793-78, it is proposed to amend 28 CFR part 16 as set forth below.


Stephen R. Colgate,
Assistant Attorney General for Administration.

1. The authority for Part 16 continues to read as follows:

   **Authority:** 5 U.S.C. 301, 552, 552a, 552b(g) and 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717 and 9701.

2. It is proposed to amend 28 CFR 16.97 by redesignating paragraph (c) as paragraph (l), by revising the first sentence of newly-redesignated paragraph (l), and by adding paragraphs (c) and (d) to read as follows:

   **§ 16.97 Exemption of Federal Bureau of Prisons Systems-limited access.**

   * * * * *

   (c) The following system of records is exempted pursuant to 5 U.S.C. 552a(j)(2) from subsections (c) (3) and (4), (d), (e)(1), (e)(2), (e)(3), (e)(5) and (8), and (g). In addition, the following system of records is exempted pursuant to 5 U.S.C. 552a(k)(2) from subsections (c)(3), (d), and (e)(1):

   Bureau of Prisons Access Control Entry/Exit, JUSTICE/BOP-010.

   (d) These exemptions apply only to the extent that information in these systems is subject to exemption pursuant to 5 U.S.C. 552a(j)(2) or (k)(2). Where compliance would not appear to interfere with or adversely affect the law enforcement process, and/or where it may be appropriate to permit individuals to contest the accuracy of the information collected, e.g., public source materials, or those supplied by third parties, the applicable exemption may be waived, either partially or totally, by the Bureau. Exemptions from the particular subsections are justified for the following reasons:

   (1) From subsection (c)(3) for similar reasons as those enumerated in paragraph (3).

   (2) From subsection (c)(4) to the extent that exemption from subsection (d) will make notification of corrections or notations of disputes inapplicable.

   (3) From the access provisions of subsection (d) to the extent that exemption from this subsection may appear to be necessary to prevent access by record subjects to information that may jeopardize the legitimate correctional interests of safety, security, and good order of Bureau of Prisons facilities; to protect the privacy of third parties; and to protect access to relevant information received from third parties, such as other Federal State, local and foreign law enforcement agencies, Federal and State probation and judicial offices, the disclosure of which may permit a record subject to evade apprehension, prosecution, etc.; and/or to otherwise protect investigatory or law enforcement information, whether received from other third parties, or whether developed internally by the Bureau.

   (4) From the amendment provisions of subsection (d) because amendment of the records would interfere with law enforcement operations and impose an impossible administrative burden. In addition to efforts to ensure accuracy so as to withstand possible judicial scrutiny, it would require that law enforcement and investigatory information be continuously reexamined, even where the information may have been collected from the record subject. Also, where records are provided by other Federal criminal justice agencies or other State, local and foreign jurisdiction, it may be administratively impossible to ensure compliance with this provision.

   (5) From subsection (e)(1) to the extent that the Bureau may collect information that may be relevant to the law enforcement operations of other agencies. In the interests of overall, effective law enforcement, such information should be retained and made available to those agencies with relevant responsibilities.

   (6) From subsection (e)(2) because primary collection of information directly from the record subject is often highly impractical, inappropriate and could result in inaccurate information.

   (7) From subsection (e)(3) because compliance with this subsection may impede access to the records of information that may be valuable to law enforcement interests.

   (8) From subsection (e)(5) because in the collection and maintenance of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely and complete. Data which may seem unrelated, irrelevant or incomplete when collected may take on added meaning or significance as an investigation progresses or with the passage of time, and could be relevant to future law enforcement decisions.

   (9) From subsection (e)(8) because the nature of Bureau of Prisons law enforcement activities renders notice of compliance with compulsory legal process impractical and could seriously jeopardize institution security and personal safety and/or impede overall law enforcement efforts.

   (10) From subsection (g) to the extent that the system is exempted from subsection (d).

   * * * * *

   (i) Consistent with the legislative purpose of the Privacy Act of 1974 (Pub. L. 93-579) the Bureau of Prisons has initiated a procedure whereby federal inmates in custody may gain access and review their individual prison files maintained at the institution of incarceration. * * *

   [FR Doc. 95-24613 Filed 10-3-95; 8:45 am]

BILLING CODE 4410-05-M

**DEPARTMENT OF THE INTERIOR**

Minerals Management Service

30 CFR Part 206

RIN 1010-AB94 and 1010-AC00

Revision of Valuation Regulations Governing Oil and Gas Transportation and Processing Allowances, and Coal Washing and Transportation Allowances

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Proposed rule; notice of extension of public comment period.

**SUMMARY:** The Minerals Management Service (MMS) gives notice that it is extending the public comment period on two Proposed Rulemakings, which were published in the Federal Register on August 7, 1995, (60 FR 40127, 40120). The proposed rules would revise the valuation regulations governing oil and gas transportation and processing allowances, and revise the valuation regulations governing coal washing and transportation allowances. MMS will extend the comment period

30 CFR Part 206

RIN 1010-AB94 and 1010-AC00

Revision of Valuation Regulations Governing Oil and Gas Transportation and Processing Allowances, and Coal Washing and Transportation Allowances

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Proposed rule; notice of extension of public comment period.

**SUMMARY:** The Minerals Management Service (MMS) gives notice that it is extending the public comment period on two Proposed Rulemakings, which were published in the Federal Register on August 7, 1995, (60 FR 40127, 40120). The proposed rules would revise the valuation regulations governing oil and gas transportation and processing allowances, and revise the valuation regulations governing coal washing and transportation allowances. MMS will extend the comment period