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VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the

proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposal would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from 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 individuals 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 the office 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:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

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).

Dated: September 29, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-24686 Filed 9-29-95; 3:31 pm]

BILLING CODE 4160-01-P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 110-95]

Exemption of Records System Under the Privacy Act

AGENCY: Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Department of Justice, Bureau of Prisons (Bureau), proposes to exempt a Privacy Act system of records from the following subsections of the Privacy Act: (c) (3) and (4), (d), (e)(1), (e)(2), (e)(3), (e) (5) and (8), and (g). This system of records is the "Access Control Entry/Exit System (JUSTICE/BOP-010)."

The exemptions are necessary to preclude the compromise of institution security, to ensure the safety of inmates, Bureau personnel and the public, to protect third party privacy, to protect law enforcement and investigatory information, and/or to otherwise ensure the effective performance of the Bureau's law enforcement functions.

DATES: Submit any comments by November 3, 1995.

ADDRESSES: Address all comments to Patricia E. Neely, Program Analyst, Systems Policy Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 850, WCTR Building).

FOR FURTHER INFORMATION CONTACT: Patricia E. Neely, Program Analyst, Systems Policy Staff, Justice Management Division, (202) 616-0178.

SUPPLEMENTARY INFORMATION: In the notice section of today's Federal

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

Administrative practices and procedure, Freedom of Information Act, Government in the Sunshine Act, and Privacy Act.

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.

Dated: September 22, 1995.

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 (i), by revising the first sentence of newly-redesignated paragraph (i), 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 jurisdictions, 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 the collection 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. * * *

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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