(e) The inspection and installation required by this AD shall be done in accordance with Air Research Technology Service Bulletin No. SB–1–96, Issue 1, dated April 11, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Air Research Technology, Inc., 3440 McCarthy, Montreal, Quebec, Canada H4K. Copies may be inspected at the FAA, Central Region, ffice of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(f) This amendment becomes effective on September 21, 1998.

Issued in Kansas City, Missouri, on July 23, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–20225 Filed 7–28–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–ACE–6]

Amendment to Class D and Class E Airspace; St. Joseph, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; withdrawal.

SUMMARY: This action withdraws the Direct final rule, request for comments mending the Class D and Class E airspace designations at St. Joseph, MO. The Direct final rule, request for comments is being withdrawn due to an error in the original Docket 98–ACE–6 (63 FR 20528), published April 27, 1998 and a delay in publication of the correction. Therefore, a determination has been made to withdraw the Direct final rule, request for comments and resubmit it at a later date.

EFFECTIVE DATE: This withdrawal is effective July 29, 1998.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, MO 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION:

The Direct Final Rule

On April 27, 1998, a Direct final rule, request for comments was published in the **Federal Register** to amend the Class D and Class E airspace designations at St. Joseph, MO. The Class E airspace, 700 feet and above was enlarged to comply with the criteria specified in FAA Order 7400.2D. The Class D and Class E surface area designations were revised to reflect a change to the Airport Reference Point. The FAA has encountered a delay in publication of an extension of comment period and a correction to Docket 98–ACE–6; therefore, it is necessary to withdraw the Direct final rule, request for comments.

Conclusion

In consideration of the aforementioned publication delay, action is being taken to withdraw the Direct final rule, request for comments until an appropriate comment period is provided.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Withdrawal of the Direct final rule, request for comments

Accordingly, pursuant to the authority delegated to me, Airspace Docket No. 98–ACE–6, as published in the **Federal Register** on April 27, 1998 (63 FR 20528), is hereby withdrawn.

Authority: 49 U.S.C. 40103, 40113, 40120; E. O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Issued in Kansas City, MO, on July 10, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–20116 Filed 7–28–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 744

[Docket No. 970428099–8185–06]

RIN 0694–AB60

Additions to Entity List: Russian Entities

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Export Administration Regulations (EAR) provide that the Bureau of Export Administration (BXA) may inform exporters, individually or through amendment to the EAR, that a license is required for exports or reexports to certain entities. The EAR contains a list of such entities. This rule adds to the entity list certain Russian entities under investigation by the Russian government for suspected export control violations involving weapons of mass destruction and missile technology. Exports or reexports of all items subject to the EAR to these newly added entities now require a license, and applications will be reviewed with a presumption of denial.

EFFECTIVE DATE: This rule is effective July 29, 1998.

FOR FURTHER INFORMATION CONTACT: Eileen M. Albanese, Office of Exporter Services, Bureau of Export Administration, Telephone: (202) 482–0436.

SUPPLEMENTARY INFORMATION:

Background

General Prohibition Five (§ 736.2(b)(5) of the EAR) prohibits exports and reexports to certain end-users or end-uses (described in part 744 of the EAR) without a license. In the form of Supplement No. 4 to part 744, BXA maintains an ''Entity List'' to provide notice informing the public of certain entities subject to such licensing requirements. This rule adds certain entities in Russia to this list. This rule further adds a new § 744.10 describing license requirements and review standards for exports and reexports to such entities.

Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the EAR in Executive Order 12924 of August 19, 1994, continued by Presidential notices of August 15, 1995, August 14, 1996, and August 15, 1997.

Rulemaking Requirements

1. This final rule has been determined to be not significant for the purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This rule involves a collection of information requirements subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694–0088.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, PO Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–744) is amended, as follows:

PART 744—[AMENDED]

1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*, 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of August 15, 1995 (60 FR 42767, August 17, 1995); and Notice of August 14, 1996 (61 FR 42527); and August 13, 1997 (62 FR 43629, August 15, 1997).

2. Part 744 is amended by adding a new § 744.10 to read as follows:

§ 744.10 Restrictions on certain entities in Russia.

(a) *General prohibition.* Certain entities in Russia, under investigation by the Russian government for suspected export control violations involving weapons of mass destruction and missile technology, are included in Supplement No. 4 of this part 744 (Entity List). (See also § 744.1(c) of the EAR.) Exporters are hereby informed that these entities are ineligible to receive any items subject to he EAR without a license.

(b) *Exceptions.* No License Exceptions apply to the prohibition described in paragraph (a) of this section.

(c) *License review standards.* Applications to export or reexport items subject to the EAR to these entities will be reviewed with a presumption of denial.

3. Supplement No. 4 to part 744 is amended by adding, in alphabetical order, the following entities:

Supplement No. 4 to part 744—Entity List

* * * * *

Baltic State Technical University, 1/21, 1-ya Krasnoarmeiskaya UI., 198005 St. Petersburg, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

Europalace 2000, Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

Glavkosmos, 9 Krasnoproletarskaya st., 103030 Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

Garfit (aka State Scientific Research Institute of Graphite or NIIGRAFIT), 2 Ulitsa Elektrodnaya, 111524 Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

INOR Scientific Center, Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

MOSO Company, Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

Polyus Scientific Production Association, 3 Ulitsa Vvedenskogo, 117342 Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

Dated: July 23, 1998.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 98–20272 Filed 7–28–98; 8:45 am]

BILLING CODE 3510–33–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 96P–0228]

Medical Devices; Reclassification and Codification of Vitamin D Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to INCSTAR Corp. reclassifying INCSTAR 25–Hydroxyvitamin D ^{125}I Radioimmunoassay (RIA). This radioimmunoassay device is intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25–OH–D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency. The device and substantially equivalent devices of this generic type were reclassified from class III (premarket approval) to class II (special controls). Accordingly, the order is being codified in the Code of Federal Regulations.

EFFECTIVE DATES: The regulation is effective August 28, 1998. The reclassification was effective September 24, 1996.

FOR FURTHER INFORMATION CONTACT: Sharon K. Lappalainen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation