

## NUCLEAR REGULATORY COMMISSION

[NRC License No. 29-30458-01]

### **SteriGenics International, Somerset, NJ: Exemption From 10 CFR 36.23(a); Environmental Assessment, Finding of No Significant Impact, and Notice of Opportunity for a Hearing**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** SteriGenics International, Somerset, NJ: Exemption from 10 CFR 36.23(a); Environmental Assessment, Finding of No Significant Impact, and Notice of Opportunity for a Hearing.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is considering authorizing SteriGenics International, Inc. (SteriGenics or the licensee) an exemption to use a cell door which prevents an individual in the radiation room from leaving.

#### **SUPPLEMENTARY INFORMATION:**

##### **Proposed Action**

SteriGenics is licensed by the NRC to irradiate materials, except explosives, flammables, and corrosives using cobalt-60 in a panoramic wet-source-storage irradiator. The licensee requested, in a letter dated September 26, 2000, that the NRC grant an exemption from 10 CFR 36.23(a) to use a cell door which prevents an individual in the radiation room from leaving. SteriGenics has been conducting irradiations using this cell door since the license was issued on February 1, 1999. The NRC staff has determined during an inspection of the facility, that the cell door does not meet 10 CFR 36.23(a) which requires that doors and barriers not prevent an individual in the radiation room from leaving.

##### **Need for the Proposed Action**

Part 36 irradiators use high activity sealed sources of radioactive material in a facility constructed so that the sealed sources and material being irradiated are contained in a shielded volume (radiation room). In many units, sources are stored under water (wet-source-storage). Irradiator facilities typically incorporate the use of a shielded "maze" which allows an individual to move to a shielded area within the radiation room and a door to the radiation room which allows an individual to exit the radiation room at any time.

The exemption is needed so that SteriGenics can carry out its business of irradiating materials in this irradiator. The door to the radiation room of this irradiator serves as an integral part of

the shielding and must be closed prior to exposing the radioactive sources to conduct an irradiation. The design of the irradiator control system does not allow the radioactive sources to be raised unless the door is closed. Once closed, an individual located in the radiation room cannot open the door and, therefore, is unable to leave the radiation room as required by 10 CFR 36.23(a). An individual in the radiation room with the door closed can prevent the sources from rising by pulling a cord on the room wall and thereby prevent radiation exposure.

SteriGenics has proposed modifications which provide a level of safety equivalent to that which is provided by compliance with 10 CFR 36.23(a). Currently, there are two pull cords inside the radiation room. One runs the length of two of the room walls, the second the length of the third. The fourth wall is covered by equipment. The presence of equipment in the radiation room forces individuals in the radiation room to be near one of these cords. Both of these cords must be actuated as part of the irradiator startup sequence. This actuation assures that the cords are functional and that the operator has searched the cell prior to beginning an irradiation. Once the startup sequence has been completed, the pull cords change function and pulling either cord will prevent the sources from rising or cause them to return to the shielded position if they have begun to rise. SteriGenics proposes to modify the irradiator control circuit logic so that if an individual pulls one of these cords twice, in addition to the sources returning to the shielded position, the cell door will open after a short delay. The control system logic will assure that the door does not open until and unless the sources are in the fully "down" position and radiation levels in the room are normal. The delay is caused by the operation of this logic and the fact that it takes between 15 and 30 seconds for the door to open.

SteriGenics will also relocate the "set-up" key switch to the far corner inside the radiation room. Currently, this switch is located outside the cell door. Inserting the key and turning this switch begins the sequence which eventually allows moving the sources. Within 90 seconds of turning the switch, the operator must search the radiation room, pull each cord once, exit the room and close the shield door. The operator must then place the key in the control console and may then move the sources. Placing the switch in the room forces the operator to bring the key which is used to move the sources (as required by 10 CFR 36.31(a)) into the radiation room

during the "set-up" process. This increases the assurance that this requirement will be met by substituting an active control for the current administrative control (the operator is required by existing procedure to take the key into the room). Taking the key into the room during "setup" assures that no one other than that operator can move the sources.

##### **Environmental Impacts of the Proposed Action**

No radioactive material is released into the environment, all of the radioactive material is wholly contained within the shielded irradiator and there will be no changes to radiation dose rates outside the irradiator. The radiation dose rate outside this irradiator meets regulatory requirements and is similar to the dose rate outside traditional panoramic wet-source-storage irradiators which meet the requirement in 36.23(a). Therefore, the modification will not result in any significant environmental impacts.

##### **Alternatives to the Final Action**

As required by Section 102(2)(E) of NEPA (42 U.S.C. 4322(2)(E)), the staff has considered alternatives to the final action including denying the exemption or requiring that SteriGenics comply with 10 CFR 36.23(a). These options were not adopted because they would provide no gain in protection of the human environment and they would be significantly detrimental to SteriGenics. Denying the exemption request would result in SteriGenics ceasing all irradiations and either redesigning and substantially modifying the physical facility or disposing of the radioactive sources and decommissioning the facility. In order for SteriGenics to comply with 10 CFR 36.23(a) they need to extensively modify the existing irradiator to incorporate a shield maze. This would be expensive and would prevent the use of the existing conveyor system, requiring additional expenditures for modifications.

##### **Alternative Use of Resources**

Alternative use of resources was considered as stated above.

##### **Agencies and Persons Consulted**

Agencies or persons outside the U.S. Nuclear Regulatory Commission were not consulted because there will be no significant impact on the environment from the proposed activity.

##### **Identification of Sources Used**

Letters from SteriGenics to the U.S. Nuclear Regulatory Commission, Region I, dated:

1. January 5, 2000 (ML003676755)
2. February 4, 2000 (ML003684178)
3. September 26, 2000 (ML003754079)

### Finding of No Significant Impact

Based on the above EA, the Commission has concluded that environmental impacts that would be created by the proposed action would not have a significant effect on the quality of the human environment and a Finding of No Significant Impact is appropriate. Accordingly, the preparation of an Environmental Impact Statement is not warranted.

### Documents

Documents submitted by SteriGenics are available for public inspection from the Publicly Available Records (PARS) component of the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room). Assistance with the Public Electronic Reading Room may be obtained by calling (800) 397-4209. The accession numbers for the licensee's documents referred to in this Assessment are listed next to the document date above.

### Opportunity for a Hearing

Any person whose interest may be affected by the issuance of this action may file a request for a hearing. Any request for hearing must be filed with the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the publication of this notice in the **Federal Register**; be served on the NRC staff (Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852), and on the licensee (SteriGenics International, 210 Clyde Road, Somerset, NJ 08873); and must comply with the requirements for requesting a hearing set forth in the Commission's regulations, 10 CFR part 2, subpart L, "Information Hearing Procedures for Adjudications in Materials Licensing Proceedings."

These requirements, which the request must address in detail, are:

1. The interest of the requestor in the proceeding;
2. How that interest may be affected by the results of the proceeding (including the reasons why the requestor should be permitted a hearing);
3. The requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and
4. The circumstances establishing that the request for hearing is timely—that

is, filed within 30 days of the date of this notice.

In addressing how the requestor's interest may be affected by the proceeding, the request should describe the nature of the requestor's right under the Atomic Energy Act of 1954, as amended, to be made a party to the proceeding; the nature and extent of the requestor's property, financial, or other (*i.e.*, health, safety) interest in the proceeding; and the possible effect of any order that may be entered in the proceeding upon the requestor's interest.

Dated at King of Prussia, Pennsylvania, this 4th day of January 2001.

For the Nuclear Regulatory Commission.

**John D. Kinneman,**

*Chief, Nuclear Materials Safety Branch 2,  
Division of Nuclear Materials Safety Region I.*

[FR Doc. 01-1173 Filed 1-12-01; 8:45 am]

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## NUCLEAR REGULATORY COMMISSION

**[Docket No. 030-28641, License No. 42-23539-01AF, Department of the Air Force; Docket No. 030-29462, License No. 45-23645-01NA, Department of the Navy; Docket No. 040-08767, License No. SUC-1380, Department of the Army]**

### Notice of Issuance of Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, has issued a director's decision with regard to a petition dated June 1, 2000, filed by Doug Rokke, Ph.D., hereinafter referred to as the "petitioner." The petition concerns the use of depleted uranium (DU) by the U.S. Department of Defense and all services.

The petition requested that the U.S. Nuclear Regulatory Commission (Commission or NRC) hold a hearing to consider "the revocation of the master DU [depleted uranium] license for the U.S. Department of Defense and all services, implementation of substantial fines and consideration of personal criminal liability." As the basis for this request, the petitioner stated that "the continuing deliberate use of DU munitions during battle and during peacetime is resulting in serious health and environmental consequences."

By letter dated September 8, 2000, and addressed to the petitioner, the NRC staff acknowledged receiving the petition, and stated that pursuant to 10 CFR 2.206 the petition was referred to the Office of Nuclear Material Safety and Safeguards for action, and that it

would be acted upon within a reasonable time.

The NRC staff requested the U.S. Department of the Air Force, the U.S. Department of the Army, and the U.S. Department of the Navy to respond to the petition. The licensees responded on October 30, 2000, and the information provided was considered by the staff in its evaluation of the petition.

The Director of the Office of Nuclear Material Safety and Safeguards has determined that the request to hold a hearing to consider the revocation of the military licenses authorizing the use of DU, implementation of substantial fines, and consideration of personal criminal liability, should be denied. The reasons for this decision are explained in the director's decision pursuant to 10 CFR 2.206 [DD-01-01], the complete text of which is available in ADAMS for inspection at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and via the NRC's Web site (<http://www.nrc.gov>) on the World Wide Web, under the "Public Involvement" icon.

A copy of the director's decision will be filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206 of the Commission's regulations. As provided for by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the decision, unless the Commission, on its own motion, institutes a review of the director's decision in that time.

Dated at Rockville, Maryland, this 9th day of January 2001.

For the Nuclear Regulatory Commission.

**William F. Kane,**

*Director, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 01-1175 Filed 1-12-01; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

**Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Bitwise Designs, Inc., Common Stock, \$.001 Par Value) File No. 0-20190**

January 9, 2001.

Bitwise Designs, Inc., a Delaware corporation ("Company"), has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934