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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-02

October 12, 2000

Thomas L. Powers, President
Sun Nuclear Corp.
425-A Pineda Court
Melbourne, Florida 32940

Dear Mr. Powers:

We are writing to you because on July 7, 10-13, 2000 FDA Investigator R. Kevin Vogel inspected your facility in Melbourne, Florida and collected information that revealed serious regulatory problems involving your firm's manufacturing of medical devices.

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm manufactures are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you manufacture are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Your firm's internal quality audits fail to adequately address all of the required areas of the Quality Systems regulation as required by 21 CFR 820.22. For example, audits conducted failed to identify major deviations from the Quality System regulation; internal audit criteria fails to include all major areas of the Quality System regulation including process validation and design controls, and proposed audit agenda(s) including the annual schedule of quality audits fail to address all required areas of the quality system for coverage to assure the system is in compliance with established Quality System requirements (FDA 483, Item # 1).
2. Management at your firm with executive responsibility failed to establish a quality policy that is understood, implemented, and maintained as required by 21 CFR 820.20. For example, the management representative was appointed but not given the authority to execute his responsibilities. There is no established management review procedure documented and management reviews are not adequate including, but not limited to, review of the organizational structure, review of purchasing controls (21 CFR 820.50), reviews of nonconforming product and complaints (21 CFR 820.90), and reviews of corrective and preventive actions taken as a result of internal quality audit results (21 CFR 820.100) (FDA 483, Item #2).
3. Your firm's corrective and preventive action (CAPA) procedure is inadequate because it fails to analyze all sources of quality data, fails to verify/validate (and document) corrective/preventive actions as required by 21 CFR 820.100. For example, your firm failed to analyze all sources of quality data including in-process rejects, repair orders, and complaints; failed to verify and/or validate corrective and preventive actions and corrective/preventive actions were not documented as required by your firm's CAPA procedure (FDA 483, Item #3).
4. Your firm failed to establish and maintain process control procedures necessary to ensure conformance to specifications as required by 21 CFR 820.70(c). For example, ESD reduction procedures have not been established to reduce or eliminate static electrical discharge that may adversely impact the quality of the product (FDA 483, Item #4).

5. Your firm failed to adequately validate software integral to the IVD, IVD wireless and [REDACTED] devices as required by 21 CFR 820.75. For example, structural testing of the software is not completed or documented, there are no software validation protocols available, and the compilers were not validated (FDA 483, Item #5).
6. Your firm failed to establish procedures identifying training needs and/or criteria to be met that ensure that all personnel are trained adequately to perform their assigned responsibilities as required by 21 CFR 820.25. For example, personnel who are responsible for hand soldering pc boards are not required to demonstrate proficiency by conducting a proscribed number of processes. Training is also not documented (FDA 483, Item #6).

MEDICAL DEVICE REPORTING

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

7. Your firm failed to develop, maintain and implement written MDR procedures as required by 21 CFR 803.17.

In addition, your firm failed to establish and maintain procedures required to control the design of device(s) to ensure specified design requirements are met as required by 21 CFR 820.30. For example, determination of the need to submit a 510(k) when introducing a new device or making changes to existing devices was not documented. Documentation of the IVD & Electrometer devices released to production in October 1997 and the QED device released in November 1997 was not available. There was no formal Design Control procedure established until May 1998 (FDA 483, Item #7).

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. You should also be aware that you may receive other correspondence from FDA concerning the status of devices that were marketed for the first time or were substantially changed without a 510(k) premarket notification being submitted to the Agency for review and clearance.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

David J. Gallant
for Emma Singleton
Director, Florida District