Interim Report

NUREG-1717 Assessment of Beta Voltaic Battery-Powered Pacemaker

SUBMITTED TO:

U.S. Nuclear Regulatory Commission

SUBMITTED BY:

Dade Moeller & Associates, Inc. and Widetronix, Inc.

April 2014

Project Goal:

Widetronix, Inc. is actively exploring the possibility of bringing a betavoltaic powered medical implant to market. We want to develop an implant that ideally, from the NRC's radiation safety standpoint, does not require patient tracking or device retrieval.

Targeted Pathway:

Widetronix believes that an exempt distribution license is required for the medical implant in order to be eligible for the required regulatory framework. Therefore, Widetronix's consultant, Dade Moeller, has performed an initial risk analysis in advance of the application based on the guidance provided in NUREG 1717 Appendix A. Our objective in this meeting is to determine the following:

- Confirm if this is the appropriate regulatory pathway; and
- Determine if the risk analysis was performed appropriately with valid assumptions.

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1.0 EXECUTIVE SUMMARY OF NUREG-1717 REVIEW

Scope of Work

Widetronix, Inc. is considering the introduction of a tritium fueled betavoltaic power source into a medical implant. In the United States, products or devices containing source or byproduct material may be distributed exempt from all radioactive materials regulations only if authorized by an exempt distribution license issued by the U.S. Nuclear Regulatory Commission (NRC). NRC document NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," provides the methodology that NRC follows in their evaluation of devices under consideration for exempt status. The document presents the dose-based evaluation for products currently approved for exempt distribution as well as the appropriate methodology for consideration of newly proposed exempt products, such as the beta voltaic powered pacemaker. Dade Moeller & Associates (Dade Moeller) was asked to evaluate the suitability of a betavoltaic enabled pacemaker for exempt distribution status based on NUREG-1717. This report includes the findings of the evaluation as well as a discussion of relevant issues going forward.

Findings

A dose analysis based on NUREG-1717 Appendix A methodology was performed covering accident, disposal, and distribution scenarios. In all cases, the data clearly support a conclusion that radiation doses due to the presence of tritium in betavoltaic enabled medical devices would fall within the range of doses caused by other products currently approved for exempt distribution status.

Next Step

Dade Moeller and Widetronix have provided this report to the U.S. Nuclear Regulatory Commission (NRC) in advance of a meeting scheduled at the NRC headquarters on April 23, 2014. During this meeting, NRC will be asked to discuss the assumptions for the dose assessment and related questions, enabling the Dade Moeller/Widetronix team to validate the assumptions used to complete the analysis and finalize this report. In addition, the meeting will allow for a discussion of regulatory issues that will impact licensing strategy.

2.0 BACKGROUND

NUREG-1717 provides the regulatory guidance for a betavoltaic enabled medical implant. These regulations cover three key areas for consideration that include dose, potential risk to public health and safety, and benefit to the public.

The body of NUREG-1717 provides a comprehensive discussion of likely doses to individuals and the population from the various products currently approved for exempt distribution. These include several items such as luminescent dials, light bulbs, and smoke detectors. It establishes a range of doses from exempt products, providing a basis of comparison for products newly proposed for exempt distribution. The doses are summarized below:

- Individual doses of 10^{-3} mrem to 20 mrem per year
- Skin doses of 10 mrem to 40 mrem to small areas of the skin per year

Under various accident and product misuse scenarios evaluated, annual doses range from 0.1 mrem to 1,000 mrem. Collective (or population based doses) are also evaluated, although these data are not applicable to a comparison to the betavoltaic enabled medical implant since that device is not currently in use.

NUREG-1717 also directs NRC to determine if the possession, use, and transfer of the proposed exempt product/material constitutes an unreasonable risk to the public health and safety. Such a determination must take into account distribution and transport of the products, product usage, and disposal. A discussion of the evaluation performed on generally licensed products under consideration for exempt distribution status includes a statement that the device must meet the safety criteria for normal use as per 10 CFR 32.51. These include:

- Under ordinary conditions, no person will receive a dose in excess of 10 percent of an annual dose limit; and
- Under accident conditions, no person will receive a dose in excess of the doses listed in column IV of the table in 10 CFR 32.24 (15 rem whole body, 200 rem extremities or skin, 50 rem to other organs).

Recently, NRC published a "Consumer Product Policy Statement" in the Federal Register (FR-2014-01-16, Vol. 79, No. 11 [NRC-2010-0292], pp. 2907 – 2912). The statement noted that all consumer products containing radioactive materials must comply with environmental considerations (as covered in 10 CFR 51) and established the following principal considerations:

- Potential external and internal exposure of individuals from handling, use, storage and disposal of individual products;
- Potential total cumulative radiation dose to individuals exposed to a number of products;
- Long-term potential dose to general population from the uncontrolled disposal and dispersal into the environment of radioactive material from products; and
- Societal benefit.

In performing a detailed evaluation of doses from consumer products, the statement identified the need to evaluate doses resulting from:

- External radiation levels;
- Proximity of the product to human tissue during use;
- Area of tissue exposed;
- Potential for dose from intakes;
- Quantity of radioactive material per product;
- The chemical form and solubility of the radioactive material;
- Containment of the radioactive material; and
- Degree of access to the product during normal handling and use.

3.0 DOSE ANALYSES

Appendix A of NUREG-1717 identifies the scenarios and exposed populations for dose-based evaluation of products considered for exempt distribution. The analysis is divided into three basic categories: accidents, disposal, and transportation/storage.

Accidents

Four types of accidents are included for evaluation, including:

- Fires resulting in release of airborne radioactivity
- Mechanical re-suspension of respirable radioactive particulates during a post-fire cleanup
- Spills of radioactive liquids or powders
- Release of radioactive gas resulting from crushing glass tubes.

The tritium used in the construction of Widetronix's betavoltaics is considered solid form as it is bound within a metal lattice and is contained securely within the device. Therefore both the spill and gaseous release scenarios are not applicable.

In modeling the scenarios to develop appropriate dose-to-source ratios, NRC uses numerous assumptions and default parameter values. These parameters include, but are not limited to, a release fraction of 0.01% for release to air of particulate activity contained within a protective device (such as a battery), a one order of magnitude reduction in the dose-to source ratio for solid form activity, ventilation rates for the populations evaluated, and size of the affected structures (truck, warehouse, residence). The results for the accident scenarios are provided in Table 1, reflecting a range of doses that NRC has deemed acceptable for products currently approved for exempt distribution.

Table 1: Dose From Accidents

Location	# of 10 Ci Batteries	Dose-to-Source Ratio (rem/Ci)	Dose (mrem)
Transport	10	8.3×10^{-6}	0.8
Warehouse	1000	1.5×10^{-6}	15
Residence	1	1.0×10^{-5}	0.1

For the purpose of performing conservative calculations, an assumption of 10 Ci tritium per betavoltaic is carried throughout the analysis. It should also be noted that the dose-to-source ratio provided for tritium is based on tritiated water; as such, they are increased by a factor of 1.5 to account for dose due to skin absorption. This "additional dose" is a conservative dose estimate, as it is unlikely that there would be complete conversion of airborne tritium released from a betavoltaic to tritiated water vapor during an actual fire.

The dose-to-source ratio tables in NUREG-1717 do not include values for particulate re-suspension of tritium, as the assumption is made that the tritium is in vapor form, making it impossible to generate doses for the post-fire particulate resuspension scenario. It is not likely that the doses would vary significantly from the doses provided in the table for the fire fighter scenario.

Disposal

Three disposal scenarios are considered in the dose assessment; they include disposal at a municipal landfill, incineration at a municipal waste incinerator, and incineration at a recycled metals facility. Populations considered include waste collectors, landfill workers, off-site members of the public, future on-site residents (landfill scenario only), and users of recycled products (recycled metal scenario only). Dose analysis results for all applicable scenarios are shown in the following table. As was the case for the accident scenarios, the results for the disposal scenarios shown in Table 2 reflect a range of doses that NRC has deemed acceptable for products currently approved for exempt distribution.

Table 2: Dose From Disposal

Scenario	# of 10 Ci Batteries	Dose-to-Source Ratio Inhalation (rem/Ci)	Dose-to-Source Ratio Ingestion (rem/Ci)	Dose (mrem)
Municipal Landfill				
Waste Collector	1,000	2.6×10^{-11}	3.3×10^{-9}	3.3×10^{-2}
Worker	1,000	3.1×10^{-12}	7.0×10^{-10}	7.0×10^{-3}
Off-site resident	1,000,000	1.1×10^{-11}	1.2×10^{-9}	12
On-site resident (future)	1,000,000	4.2×10^{-14}	1.2×10^{-12}	1.2×10^{-2}
Municipal Incinerator				
Waste Collector	1,000	6.1×10^{-10}	7.8×10^{-8}	0.8
Worker	1,000	1.7×10^{-12}	2.1×10^{-11}	2.3×10^{-4}
Off-site resident	1,000,000	1.0×10^{-10}	--	1.0
Metal Smelter				
Slag Worker	1,000	--	1.8×10^{-8}	0.2
Off-site resident	1,000,000	1.9×10^{-10}	--	1.9

Numerous assumptions are used in the NUREG-1717 Appendix A models for numerous parameters, such as inhalation and ingestion rates, number of landfills used to dispose product, respirable fraction of particles, mass of waste per waste container, and exposure time. Additional assumptions are that waste collectors, landfill workers, and workers at a metals recycling facility might encounter tritium released from 1,000 batteries, and current and future residents might encounter tritium released from 1,000,000 batteries. The dose-to-source ratios generated are conservative relative to the tritium that would be released from betavoltaic batteries due to the low degree of dispersion that would be anticipated from solid form material resident within a protective container (the power source).

Distribution

NUREG-1717 Appendix A considers dose scenarios resulting from the distribution of the product, including commercial truck (large and small), warehousing, retailing, and air transport. For commercial truck transport, the dose analysis considers the exposure scenario (highly exposed when the package is near the driver versus average exposed when the package is centrally located in the cargo area), and the duration of delivery (local vs. regional). Additionally, storage of product in both large and medium-sized warehouses is included in our

analysis. For air transportation, dose is considered to persons coming in contact with the product in the freight terminal and on an airplane. Retailing is not applicable to our evaluation of the betavoltaic in the medical implant scenario.

The results from the various applicable distribution scenarios are presented in Table 3; they too are consistent with the range of doses that NRC has deemed acceptable for products currently approved for exempt distribution.

Table 3: Dose From Distribution

Type	# of 10 Ci Batteries	Dose-to-Source Ratio (rem/Ci)	Dose (mrem)
Commercial Truck	1,000	1.2×10^{-5}	120
Warehousing	1,000	1.0×10^{-6}	10
Air Transport			
Freight terminal	1,000	1.4×10^{-6}	14
Airplane	1,000	2.4×10^{-7}	2.4

For commercial truck transport and warehousing, the doses are provided for the situations involving maximum dose-to-source factors provided in NUREG-1717 Appendix A. For each scenario, the dose-to-source factors are provided and used to calculate scenario-specific doses, based on the assumption that the cargo contains 1,000 betavoltaic enabled pacemakers.

4.0 REGULATORY PATH FORWARD

To get the device to the market exempt from regulation, two things have to happen. The United States Food and Drug Administration (FDA) must approve an application to establish the product as a medical device; this conclusion is based on a finding that the device is beneficial for human use. And the NRC must approve an application to license the device for exempt distribution. The two agencies have a memorandum of understanding in place, which establishes that FDA looks only at the benefits of the device while NRC looks at radiation safety as it relates to members of the public and the environment. The NRC will not issue a decision on an exempt distribution license until the FDA first approves the device for medical use. However, the typical procedure is to submit both applications at the same time such that the agencies do their review in parallel. In most cases, as soon as FDA issues their approval, NRC is ready to issue their decision to approve or reject the exempt distribution license application.

The NUREG-1717 Appendix A analyses described in this report would be included in the exempt distribution application. As part of the application review, NRC will evaluate the application of NUREG-1717 for accuracy, completeness, and appropriateness of assumptions. Often during a license application evaluation, NRC will request additional information and clarifications from the applicant prior to issuing a final ruling.

The Federal regulations related to exempt devices do not provide specific guidance related to betavoltaic enabled medical implants. These regulations specifically call out the *functional uses* of the radioactivity in exempt devices (e.g., light). The first citation, 10 CFR 30.22 doesn't include 'electric power generation,' 'powering a medical implant, or anything that covers the intended use. The second citation, 10 CFR 32.11.c, specifies that exempt devices are a, "…product or material is not likely to be incorporated in any…product designed for…application to, a human being." Therefore, it is likely that in the application a request to NRC for an exemption from these requirements will be necessary. For the purposes of this evaluation, the NRC technical reviewers are likely to involve NRC counsel in evaluating the request for regulatory exemption.

Another unknown at this point is whether or not an application for a sealed source and device registration (SSDR) application would need to be submitted to NRC in advance of an application for exempt distribution. SSDR applications typically contain much of the same information as do exempt distribution applications (in the absence of a SSDR) related to product construction, testing, and quality assurance. Should NRC require that the device be registered, the SSDR certificate would then be referenced in the exempt distribution license application. Historically, manufacturers and distributors have been successful obtaining SSDR certificates and exempt distribution licenses for products and devices that have more than one model or configuration. It is likely that NRC would entertain an application for a group of devices incorporating the same betavoltaic battery, as long as the testing data included all possible commercial configurations. Once a SSDR certificate and license are issued, the licensee is able to apply for amendments when updated models are developed or new configurations are desired. Amendment requests are typically much less rigorous than initial applications, since much of the initial application content remains relevant. It would be beneficial to ask for further clarification from NRC on this topic.

5.0 QUESTIONS FOR NRC CONSIDERATION

1. Is the risk analysis described above appropriate given the guidance provided in NUREG-1717 Appendix A?
    a. Would the NUREG-1717 analysis require evaluation of additional scenarios? Which ones? Different parameter values?
    b. How should typical end-of-life scenarios for medical implant devices be accounted for?
        i. Reduce to scenarios described in NUREG 1717?
        ii. If no reduction possible, what are the new scenario(s) that are "equivalent," so it will be comparable to the NUREG 1717 scenarios?
    c. If a medical implant is approved for exempt distribution, what happens when a person dies with an implanted device?
        i. Can the device be placed with the body into a cemetery?
        ii. Under what circumstances could the body and device be cremated?
        iii. If removed prior to burial or cremation, does it retain exempt status for disposal?
2. What is involved in requesting/obtaining exemptions from the regulations related to exempt products for human use?
    a. Should a sealed source and device registry (SSDR) application be submitted in advance of an exempt distribution license application for a medical implant?
3. For both SSDR and exempt distribution licenses – what is NRC policy related to combining multiple models, devices, etc. under the same certificate or license?
    a. Given the above, what would be involved when a licensee wants to add a new device using the same betavoltaic power source to an existing SSDR and license?