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Planetary Protection Concerns During Pre-Launch Radioisotope Power System Final Integration Activities

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Abstract. The Advanced Stirling Radioisotope Generator **(**ASRG) is a next-generation radioisotope-based power system that is currently being developed as an alternative to the Multi-Mission Radioisotope Thermoelectric Generator (MMRTG). Power sources such as these may be needed for proposed missions to solar system planets and bodies that have challenging Planetary Protection (PP) requirements (e.g. Mars, Europa, Enceladus) that may support NASA's search for life, remnants of past life, and the precursors of life.

One concern is that the heat from the ASRG could potentially create a region in which liquid water may occur. As advised by the NASA Planetary Protection Officer, when deploying an ASRG to Mars, the current COSPAR/NASA PP policy should be followed for Category IVc mission. Thus, sterilization processing of the ASRG to achieve bioburden reduction would be essential to meet the Planetary Protection requirements. Due to thermal constraints and associated low temperature limits of elements of the ASRG, vapor hydrogen peroxide (VHP) was suggested as a candidate alternative sterilization process to complement dry heat microbial reduction (DHMR) for the assembled ASRG. The following proposed sterilization plan for the ASRG anticipates a mission Category IVc level of cleanliness. This plan provides a scenario in which VHP is used as the final sterilization process.

Keywords: Advanced Stirling Radioisotope Generator (ASRG), Planetary Protection (PP), Vapor hydrogen peroxide (VHP) sterilization.

INTRODUCTION

Radioisotope power systems (RPS) have been essential to the U.S space program for over 50 years and have supported more than 20 missions. RPS provides electric power to spacecraft systems and science instrumentation by converting the heat produced from the natural radioactive decay of plutonium-238 to power. As there is a limited supply of ^{238}Pu and there are currently no U.S. facilities producing it in significant quantities, NASA must consider the limited supply when planning future RPS powered missions (1).

The most recent RPS technology to support an exploration mission is the Multi-Mission Radioisotope Thermoelectric Generator (MMRTG), which is currently providing power to the Mars Science Laboratory (MSL) rover. NASA and the DOE are now developing an Advanced Stirling Radioisotope Generator (ASRG), which utilizes a highly efficient Stirling engine for conversion of heat to electric power. ASRGs should be able to provide power comparable to the MMRTG, but with only one quarter of the ^{238}Pu. The higher radioisotope fuel efficiency provided by the ASRG could extend the supply of ^{238}Pu available for future missions (2).

In the development of the ASRG, the most stringent mission requirements have been considered to ensure multi-mission support capabilities. Planetary Protection (PP) requirements vary depending on a missions target planetary body and science goals. The ASRG PP planning team has considered what would be required to support a mission to Mars where liquid water may be present. This would be a PP Category IVc mission per NPR 8020.12D (3) and is one of the most challenging missions from a PP perspective.

Category IVc mission requirements are largely based on the biological cleanliness precedent set by the Viking missions, which were powered by previous generation RPS. Satisfaction of PP requirements for RPS technology prior to ASRG was relatively simple as the power system either generated enough heat to be self-sterilizing or could

withstand the temperatures required to appropriately reduce the systems bioburden. Due to thermal constraints and associated temperature limits of elements of the ASRG, vapor hydrogen peroxide (VHP) has been considered as a sterilization process to complement Dry Heat Microbial Reduction (DHMR) for different steps in the assembly of the ASRG and for use directly prior to spacecraft integration (4, 5). A proposed plan and unique considerations for the use of VHP as the final sterilization process follows.

VHP STERILIZATION BACKGROUND

The VHP sterilization process is considered as a low temperature complementary surface sterilization technique to the NASA approved dry heat sterilization process. The VHP process employs hydrogen peroxide vapor to destroy microbes. It is widely used by the medical industry to sterilize surgical instruments and biomedical devices. The Jet Propulsion Laboratory (JPL) has developed the vapor phase hydrogen peroxide sterilization process for acceptance as a NASA approved sterilization technique for spacecraft subsystems and systems.

In the past decade, extensive validation studies were conducted by the Biotechnology and Planetary Protection Group (BPPG) at JPL and by the U.K. Health Protection Agency (under contract with the European Space Agency) (6-12). NASA/ESA formal review of vapor hydrogen peroxide specifications for bioburden reduction was conducted at NASA HQ and JPL. Certification study results were presented by both JPL and HPA scientists to the NASA and ESA Planetary Protection Officers and the review panel. The specification for use of VHP has been established and reviewed, though not yet formally published. A NASA/ESA specification for use of VHP has been approved by the Planetary Protection Officer. The following is a draft of the proposed specification for VHP sterilization processing:

The D10 value for hydrogen peroxide reduction of surface spore burden is 200 (mg/L) sec. D10 (expressed as concentration over time) is the value required to destroy 90 per cent of the microbial population on surfaces subjected to vapor hydrogen peroxide processing at a concentration of 1.1mg/L, a temperature of between 25°C and 45°C, and with relative humidity controlled between 3-50%, as measured at 35 ^{o}C. All microbial spore populations located on spacecraft “free” surfaces (i.e., such that vapor exchange can take place) and vegetative organisms are understood to be killed at this level of exposure.

The effect of the VHP process is cumulative (i.e. a Ct value of 600(mg/L)s gives 3 log reduction) with an acceptable range of application between 2 log reduction and 6 log reduction. Process application to attain more than 6 logs reduction must be supported by additional data and approved by the PPO. Surface cleanliness of hardware to be sterilized must be assessed and consistent with ISO 8 (Class 100,000) cleanroom conditions. Material compatibility and residue issues must be considered in the design of sterilization cycles. The project shall specify methods for the measurement of the time, hydrogen peroxide concentration, and humidity parameters and make allowances for stabilization times. C and t are measured real time during the exposure run. Process efficacy shall be demonstrated through the use of validated biological indicators (*B stearothermophilus* DSMZ5934/ATCC7953 or other to be selected in consultation with the PPO). The biological indicator configuration shall represent a conservative challenge compared to the hardware bioburden reduction credit claimed for the process.

VHP MATERIAL COMPATIBILITY

One of the characteristics of the hydrogen peroxide process is that it is compatible with a wide range of materials. However, there are materials that are incompatible with VHP process. These materials either compromise the efficacy of the sterilization process or the material itself is degraded/damaged by the VHP process in term of structural integrity or performance (6, 10, 14-16).

Since hydrogen peroxide is a strong oxidizer, it is important to ensure that spacecraft materials are not damaged during the sterilization process. The compatibility of ground support equipment (GSE), infrastructure, and flight hardware components with the VHP process should be evaluated on a case-by-case basis. The lowest-risk approach would be to subject a completed flight-like hardware to the complete sterilization cycle and then test the performance before committing the flight hardware to the sterilization process. If this is not a viable option, it is very important to gain as much information as possible about the VHP compatibility of flight hardware.

Validation studies conducted by the Biotechnology and Planetary Protection Group (BPPG) at the Jet Propulsion Laboratory (JPL) have generated recommendations for experimental setup, exposure conditions and test protocols for the VHP process specification (9, 11, 12, and 17). These VHP process specifications have been used as a guide for VHP exposure conditions and VHP compatibility test protocols. Over 90 spacecraft-related materials were tested for VHP compatibility by JPL in these studies (6, 10, and 13). The results of these studies are summarized (18) and could be used as reference for a future ASRG VHP compatibility evaluation.

ASRG VHP STERILIZATION AT VIF

The premise of planetary protection for the ASRG is that all internal components are cleaned to appropriate levels, assembled in a clean room, heat sterilized and not re-contaminated during the fueling process. A vapor hydrogen peroxide (VHP) atmosphere is present in the enclosed fueling facility at Idaho National Laboratory to preclude recontamination of the ASRG's internal parts (3).

Post fueling activities such as thermal vacuum, vibration testing and storage at the INL, truck transport to KSC, storage in the power source processing facility (RTGF), integration and checkout in the Payload Hazardous Servicing Facility (PHSF), transport to the vertical integration facility (VIF) and lifting up into the VIF, would present unsterilized environments. It is therefore postulated that final external surface sterilization of the ASRG would be accomplished once at a desired work level at the VIF (at the fairing access doors) and prior to spacecraft integration.

VHP Compatibility Evaluation

Before committing ASRG to VHP sterilization process, the VHP material compatibility should be evaluated for all the materials that will be in contact with VHP during the process. Leak testing has to be performed to ensure no VHP vapor penetration in to the parts/subsystem that may not be compatible with VHP process.

ASRG Bioburden Evaluation before VHP Process

The ASRG bioburden level would be evaluated before VHP process. The test would be based on the NASA NHB5340.1 process for monitoring microbiology contamination of space hardware.

Vapor Hydrogen Peroxide Generator

The Steris VHP 1000 ARD would be used as the vapor hydrogen peroxide generator. It has been used by ESA for an ambient atmosphere (as opposed to under vacuum) VHP validation study. The ARD is designed as a mobile system to be moved to different locations for room or laboratory decontamination. The ARD operates with a VHP sensor for feedback control to maintain a fixed concentration of VHP in a fixed space. The sensor bundle also monitors temperature and humidity in the space. The Steris VHP 1000 ARD system consists of VHP 1000 ARD bio-decontamination unit, dryer regenerator, high capacity dryer tank or dryer cartridge, sensing unit, auxiliary aeration unit (high capacity catalytic converter), room circulation unit and contactor unit (Figure 1).

Figure 1. STERIS VHP 1000 ARD.

VHP Enclosure for ASRG sterilization

A large VHP enclosure would be used (Figure 2). The size of the enclosure would depend on the configuration of the installation cart and spacecraft. The test enclosure consisted of a steel frame, double-walled on top and sides with low density polyethylene sheeting and Tyvek duct tape. Adhesive plastic sheeting was used for the floor of the chamber. A large removable door will provide access for moving in the hardware. The test enclosure will also be tested for compatibility with the spacecraft environmental requirements (ESD, humidity, etc.). The layout of the ARD connected with the test enclosure is also shown in Figure 2.

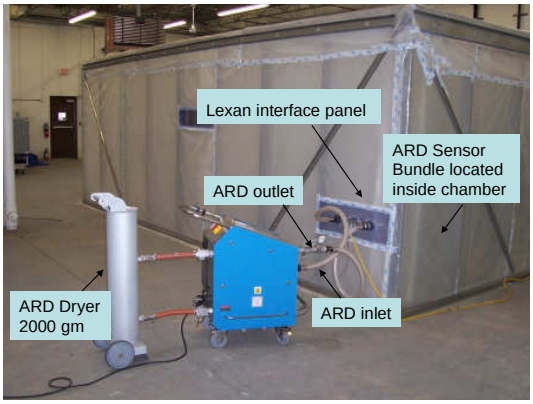

Figure 2. STERIS VHP 1000 ARD Connected with Test Enclosure

VHP Enclosure Cooling System

A Fans/Heat Exchanger would be used as the cooling system to ensure no over heating of the ASRG system during VHP sterilization. The size of the heat exchanger would be 1.02 m^2 and the airflow in the enclosure will be 0.15 m/s. The temperature of the coolant outlet would be at 22^{o}C. Both outlet and inlet of the coolant line would be insulated to ensure no cold spots in the enclosure. This cooling system would remove 500W of heat, which is generated by the ASRG, during the VHP process. The targeted temperature in the VHP enclosure is 35^{o}C. The proposed layout of the Fans/Heat Exchanger is shown in Figure 3 below.

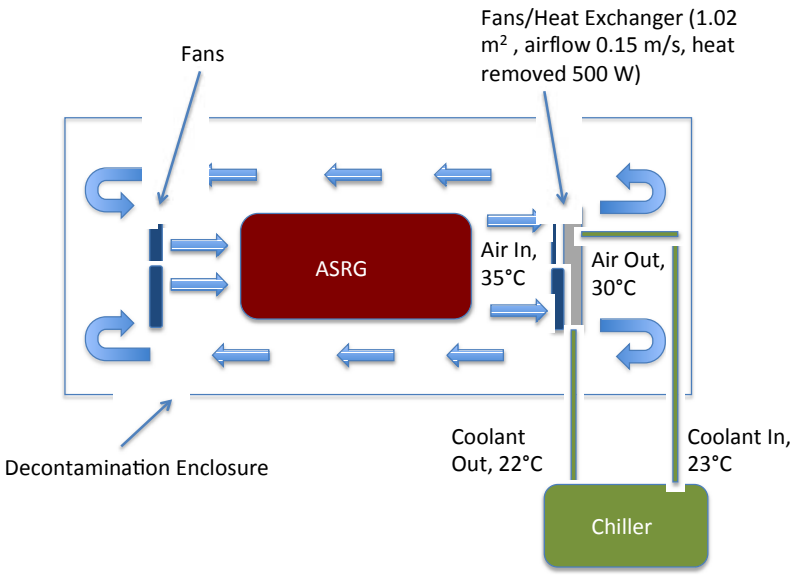

Figure 3. Fans/Heat Exchanger Layout

VHP Sterilization Process

Before VHP sterilization, the hardware should be properly grounded to ensure no ESD damage during the VHP process. The VHP process consists of four distinct phases: dehumidification, conditioning, decontamination and aeration. The following sections provide a description of these phases.

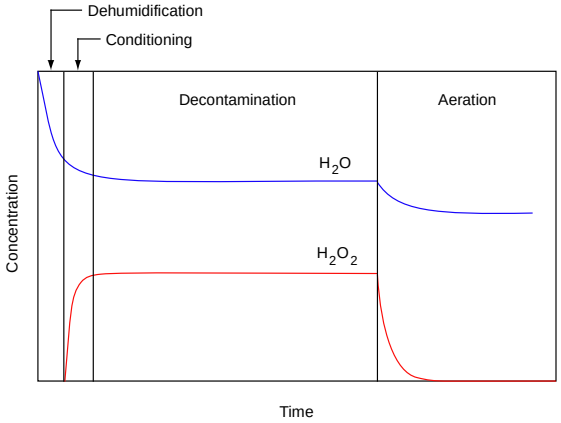

Figure 4. Phases of the VHP Decontamination Process

Dehumidification

At the start of the VHP process, the system draws air from the enclosure to be decontaminated, passes the air through the air drying module and returns it to the enclosure. Cycling the air through the dryer lowers the humidity within the enclosure to preclude the possibility of condensation of hydrogen peroxide from the vapor. Dehumidification continues until the humidity has been lowered to below the target humidity level before transition to the next phase of the cycle. The targeted humidity level for VHP sterilization is as low as 35%, but for ESD safety reasons, the setpoint for the ASRG VHP process is 40%.

Conditioning

Once the humidity threshold has been met, the VHP system then initiates injection of hydrogen peroxide vapor into the enclosure. In the conditioning phase, a rapid injection rate is usually selected so that the concentration of hydrogen peroxide is raised to the desired decontamination concentration as quickly (but uniformly throughout the chamber) as possible. When the decontamination threshold has been attained, the VHP process enters the decontamination phase. This level is monitored for active feedback control by a hydrogen peroxide sensor located within the enclosure. The targeted VHP concentration in the enclosure (measured as close as is practicable to the ASRG) is 750 ppm.

Decontamination

Once the target concentration of hydrogen peroxide is consistently maintained, the decontamination timer is started. The time required for the decontamination of the contents of the enclosure is driven by the hydrogen peroxide concentration and the required level of microbial inactivation. For a six log reduction in bioburden level with VHP concentration at 750 ppm, the decontamination time is 20 min. An additional 6 min 40 sec (two log) margin will be applied to the decontamination duration.

Aeration

After the successful completion of the decontamination phase, the VHP system ceases injection of hydrogen peroxide. Vapor from the enclosure is cycled through the catalyst to reduce the hydrogen peroxide level before returning to the enclosure. The aeration continues until the concentration of hydrogen peroxide vapor returns to ambient levels to permit opening the enclosure for retrieval of the contents.

Biological Indicators (BI)

Biological indicators would be included with the VHP sterilization process to validate the efficacy of the sterilization cycle. The biological indicators each contain 10^6 spores from a VHP resistant bacterial strain (B *stearothermophilus* DSMZ5934/ATCC7953 or other to be selected in consultation with the NASA PPO). The biological indicator configuration shall represent a conservative challenge compared to the hardware bioburden reduction credit claimed for the process.

Viable spores on unexposed (control) coupons and on the VHP exposed coupons would be enumerated by incubating in Tryptic Soy Broth (TSB) at 55°C for 48 hours. Clear tubes (no growth) indicate success of the sterilization process.

Post Sterilization Handling and Storage

All personnel working with the hardware need to be made aware of the need to retain sterility of the hardware, post sterilization processing. The ASRG hardware could be kept in the VHP enclosure after the VHP sterilization process until spacecraft integration. The fan/heat exchanger would remain operating to ensure no overheating of the ASRG system.

Re-sterilization

Some effects of VHP sterilization are cumulative. These could increase the risk of degradation of hardware performance after numerous process cycles. It is important that re-sterilization options should be carefully reviewed before committing the hardware to further sterilization.

CONCLUSION

Unlike previous RPS technologies, due to thermal constraints, the ASRG will require a treatment other than DHMR for bioburden reduction. The proposed plan presented here for the use of VHP as a final sterilization outlines the necessary considerations and detailed treatment parameters prior to final spacecraft integration activities. Additional PP implementation details during and after spacecraft integration will be determined once a mission is selected.

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