January 11, 2021

Nicolas B Campanella  
Chairman, President & CEO  
Sun Pacific Power Corp  
Medrecycler-RI, Inc.  
215 Gordons Corner Road  
Manalapan, NJ 07726

Re: Notice of Intent to Approve - Medical Waste Treatment Facility  
Medrecycler-RI, 1600 Division Road, West Warwick, RI

Dear Mr. Campanella,

The Office of Land Revitalization and Sustainable Materials Management (LR&SMM) has reviewed your re-submission dated 8/18/2020 as modified on 11/6/2020, 11/24/2020 and 11/30/2020, and 12/2/2020. The purpose of this letter is to communicate the Department’s intent to approve the license pursuant to R.I.G.L. 23-18.9-9 and this letter is not the issuance of the facility license at this time. Rather, it is the result of a final review of your application and the initiation of the statutorily mandated public hearing process.

The process following this Notice of Intent to Approve the license provides an opportunity for the public to comment on the license application and for the Department and the applicant to address substantive comments received from the public. Upon your receipt of this document Medrecycler-RI shall publish the enclosed Public Notice in the Providence Journal. Copies of the notice shall be provided to the Kent County Daily Times, the Warwick Beacon, and the East Greenwich Pendulum. A copy of the published notice shall be sent to this office. Within fifteen (15) days of the date of this Notice of Intent to Approve, the Department will hold an informal informational workshop for the public on the information submitted to date. As part of this workshop, the applicant will make a presentation about the proposed facility and answer any questions.

Between sixty (60) and seventy-five (75) days from the date of this Notice of Intent to Approve, the Department will schedule a formal public hearing to receive verbal and/or written comments from all interested parties on the pending application and Notice of Intent to Approve. This hearing will be solely for the purpose of taking formal comments and compiling an administrative record on your application, and is not intended to be a question and answer session.
Following the public comment hearing the Department will continue to accept formal written comments from all interested parties on the application and comments received at the hearing for an additional thirty days. The applicant may also submit written comments or information that they feel will address any public comments or concerns regarding your application. Once this post-hearing thirty (30) day comment period is closed, the LR&SMM will issue a response to substantive comments received and a final decision on the license application within ninety (90) days.

This tentative approval is, and the proposed license, if issued, will be subject to the following conditions, the violation of which shall constitute a violation of the license:

1. Medrecycler-RI shall fully comply with all applicable safety, zoning requirements and local ordinances of the City of West Warwick as well as all applicable state and federal regulations. A fully adjudicated violation of any of these shall constitute a violation of the license.

2. The Contingency Plan shall be approved in writing by the West Warwick Fire Department prior to accepting waste.

3. Medrecycler-RI shall provide a financial assurance mechanism compliant with the Regulations, and approved by the Department, prior to accepting waste. This shall contain a detailed cost estimate that includes an independent third-party quote for cleaning, packaging, shipping and disposal of the maximum permitted capacity of medical waste at the facility, decontaminating and decommissioning all equipment, and verification of closure by a certification of closure from a qualified professional approved by the Department. Medrecycler-RI shall operate the facility in strict compliance with the Rhode Island’s Medical Waste Regulations (250-RICR-140-15-1), RIDEM’s Solid Waste Regulations (250-RICR-140-05), as well as the Rhode Island Department of Health’s Rules and Regulations for Radiation (216-RICR-40-20). No approvals granted in this License, other than those specifically identified as variances, shall be construed as, or constitute a waiver of, or exemption from, the Act or the Regulations. Where any part of this License is seen to conflict with the requirements of the Act or the Regulations, and is not specifically identified as a variance, the requirements of the Act and/or the Regulations shall be controlling. The final license application, reflecting the amendments and clarifications submitted on December 2, 2020, is considered to be part of this License.

4. Medrecycler-RI shall only accept Regulated Medical Waste that is packaged, marked, labeled and transported in accordance with the Regulations. This shall only include solid waste incidentally mixed and packaged with the Medical Waste by the generator. Other forms of solid waste shall not be accepted by the facility without written authorization by the Department. Any unacceptable waste shall be managed in accordance with applicable regulations for that waste. The Department shall be notified of attempted delivery of unacceptable waste with 72 hours.
5. Medical waste shall be accepted only from vehicles permitted by the RIDEM/LR&SMM to transport medical waste. The Facility shall verify that the vehicles are permitted prior to accepting the waste.

6. Medrecycler-RI shall not accept hazardous waste as defined by the Rules and Regulations for Hazardous Waste Management (250-RICR-140-10-1).

7. Medrecycler-RI shall maintain accurate records for all medical waste transported from generating facilities to the Facility and keep the signed copies of all tracking documents for at least 3 years.

8. Medrecycler-RI shall store the medical waste in a secure manner and process the received medical waste within 14 days. At any time, no more than 20 containers of regulated medical waste shall be stored inside the facility; no more than 25 trailers of regulated medical waste shall be onsite. Medrecycler-RI shall accept no more than 70 tons/day of waste.

9. Prior to acceptance of Regulated Medical Waste, Medrecycler-RI shall perform pre-operational testing of the system to verify that treatment and containment of the waste is sufficient to protect workers as well as the general public from exposure to pathogens. This testing, including the specific methods and procedures to be used, shall only be conducted after approval by the Department.

   A. Medrecycler-RI shall submit detailed testing protocols for the pre-operational testing. The pre-operational testing protocols must provide specific details, in addition to the submission of November 6, 2020 entitled Macerator Biological Testing Protocol. This more detailed plan shall be developed and certified by a Certified Industrial Hygienist that provides detailed testing protocols, number of samples, etc. for the following tests:

   i. **Pressure and temperature testing of the macerator, conveyor and pyrolyser**: As proposed in the Application as modified on December 2, 2020, this test must demonstrate that temperatures and negative pressures are achieved sufficient to provide containment of the shredded waste as well as thermal treatment of the system prior to maintenance.

   ii. **Pyrolysis Unit efficacy testing**: Medrecycler-RI shall perform testing of the pyrolysis system to demonstrate the system completely and reliably inactivates *Geobacillus stearothermophilus* spores at a 4 Log10 reduction or greater.

   iii. **Macerator Containment and Decontamination Testing**: The purpose of this testing is to use biological surrogates to determine if the macerator system allows escape of microbes and to test if the decontamination procedures to allow maintenance of the macerator achieves sufficient biological inactivation through thermal and/or chemical treatment. The steps of testing shall be substantially equivalent to the following:

      1. Inoculate simulated medical waste by spraying on the biological surrogate *Geobacillus stearothermophilus* in liquid suspension at
an offsite location and double bagged in sealed containers to prevent contamination.

2. Take swab samples of inside and outside of macerator for control purposes after cleaning but before introduction of simulated waste.


4. After processing, swab samples on several locations outside of macerator and outside of tubing that conveys materials to pyrolyser.

5. Perform proposed disinfection of macerator to simulate shutdown for maintenance.

6. After disinfection open macerator and take swab samples at several locations within macerator and within conveyance tube.

7. All samples shall be sent to the lab for standard independent analysis for *Geobacillus stearothermophilus*.

B. Following Department approval of the protocols, pre-operational testing shall be performed and validated by a qualified, independent third party professional with laboratory results being sent directly to the Department.

C. Prior to instituting initial testing, Medrecycler-RI shall give the Department 72 hours notice, so that Department staff may attend and observe testing.

10. Medrecycler-RI shall submit detailed protocols for routine testing of the system at least every 40 hours of operation, and shall maintain records of this testing for at least three years.

11. Medrecycler-RI shall notify the Department of arrangements for disposal of any residuals or by-products generated the facility and shall keep records of the disposal of these wastes for at least three years.

12. The facility shall report any noncompliance that may endanger human health or the environment to the Department immediately, and shall also submit a written report within 24 hours from the time the facility becomes aware of the circumstance. This shall include information concerning release of any hazardous material, all incidents related to fires, medical waste spills that are greater than one cubic yard or failure of personal protective equipment and safety protocols. A written report shall be submitted within two business days detailing the incident and its cause; the exact dates and times, if the non-compliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance. The report shall contain all information described in the reporting section of the facility’s Contingency Plan.

13. The facility shall provide RIDEM, its authorized officers, employees, and representatives, and all other persons under Department oversight, an irrevocable right of access to the facility at all reasonable times for the purposes of performing inspections, investigations, testing and examining records. RIDEM inspectors or other authorized designated
personnel shall have the right to access the facility at all reasonable times for the above stated purposes without prior notice. Refusal to allow reasonable inspections, tests and investigations shall constitute valid ground for denial, revocation or suspension of a license; denial, revocation or suspension of a registration; and/or issuance of a Notice of Violation with Administrative Penalty.

14. The Licensee shall reimburse the Department for facility oversight costs. Said cost may include, but shall not be limited to, inspections, testing, and validation procedures, during and after pre-operational start-up; and may include any third party oversight contractors retained by the Department for said purposes.

As a result of comments received during the comment period, the Department reserves its rights to issue a denial or approval of the final application. A final approval may involve additional or amended conditions on the license, and substantive changes to these proposed conditions may require additional public notice.

Please feel free to contact Mark Dennen or Yan Li at (401) 222-4700 if you have any questions regarding this letter.

Sincerely,

Leo Hellested, P.E., Administrator
Department of Environmental Management
Office of Land Revitalization & Sustainable Materials Management

CC: Yan Li, LR&SMM/DEM
    Mark Dennen, LR&SMM/DEM
    Susan Forcier, Esq. RIDEM
    Terrence Gray, P.E. Associate Director, RIDEM