DOE-ID NEPA CX DETERMINATION
Idaho National Laboratory

CX Posting No.: DOE-ID-INL-20-163 R1

SECTION A. Project Title: SHINE Medical Technologies Radiolysis Studies

SECTION B. Project Description and Purpose:

Revision 1:

This revision identifies additional work scope and removes period of performance.

SHINE Medical Technologies, Inc. is improving its process for manufacture of its no-carrier-added Lu-177 radioisotope product using a novel chelator in the separation from the irradiated target. Scaling this process requires an understanding of the rate(s) of radiolysis of the chelator and how a radiolysis mitigator may be employed to protect the chelator from significant damage. The INL Center for Radiation Chemistry Research has the best known capabilities for testing molecular radiolysis in solution. The best approach that SHINE has afforded is irradiation of a limited number of samples at a commercial facility and in-house testing. SHINE's in-house testing requires months of development and analysis. SHINE is not equipped with the instrumentation (e.g., LC-MS) nor the expertise necessary to accurately measure and evaluate molecular kinetics and speciation from gamma radiation in solution.

The purpose of the proposed feasibility experiment is to measure the rates of chelator radiolysis in aqueous solution with and without ascorbic acid as a potential radiolysis mitigator during a Yb/Lu separation with large activity targets for process improvement. Initial experiments will determine if the use of ascorbic acid as a radiolysis mitigator is feasible in a practical concentration range for the separation. If the feasibility experiments are successful, the scope may be extended to a larger study of the kinetics and speciation of the chelator.

The feasibility study will be carried out at INL to assess the utility of ascorbic acid as a radiolysis mitigator for the novel chelator in a defined practical concentration range for the SHINE separation. This study will entail solution preparation by SHINE and shipment of those vials to INL for the experiments. These solutions will be used to develop analysis methods and carry out analysis of irradiated samples in the presence of a proposed radiolysis mitigator. Experiments at INL will consist of irradiation of the vials in dose rate calibrated geometries in a suitable gamma irradiator. Samples will be irradiated at timepoints identified to encompass a range of the mitigator and metal-bound chelator equilibrium concentrations to assess whether the proposed mitigator (ascorbic acid) is effective.

LC-MS method development will be carried out by INL and based on SHINE HPLC-UV methods for metal-bound chelator. Analysis of the irradiated samples will employ these LC-MS methods to measure the extent of radiolysis of metal-bound chelator (hereafter defined as the analytes in the context of chemical analysis).

If the feasibility experiments are successful, the scope may be extended to a more extensive study of the kinetics and speciation of the chelator. The scope of that study will be defined by the results of the feasibility study.

Phase 1: Feasibility Study

Task 1 (SHINE): Materials/Solution Preparation – Aqueous solutions of chelator and metal-bound chelator will be prepared. These will be shipped to INL along with ascorbic acid to be added to solutions as needed. This task should be complete in a week of study initiation.

Task 2 (INL): Methods Development – LC/MS method(s) for determination of metal-bound chelator will be initiated with information from SHINE HPLC methods. The method(s) should be able to measure the chelator-based analytes and be selective in the absence/presence of ascorbic acid. The developed methods will then be utilized to evaluate whether the analytes can be measured after irradiation of the solutions with and without ascorbic acid. Adjustments to LC/MS method(s) should be considered to optimize the methods for this specific task. This task may require an estimated 3 weeks to complete.

Task 3 (INL): Sample Irradiation – Gamma irradiations on solutions prepared by SHINE will take place at INL. The initial irradiations may coincide with Task 2, as to support the evaluation of whether the method(s) can effectively measure the metal-bound chelator after moderate absorbed dose (up to 15 kGy). A set of irradiations shall be carried out on samples containing between 0 and 100 mM ascorbic acid. These samples will be referred to as the "feasibility samples". This task may require 40 hours of personnel and irradiator time.

Task 4 (INL): Sample Analysis – Feasibility samples shall be analyzed by the optimized LC/MS method(s) to determine radiolysis rates of the analytes and assess to what extent ascorbic acid can mitigate radiolysis of the primary chelator species in solution, particularly the metal-bound chelator.

Phase 2: Kinetics and speciation study including unbound chelator to be considered in the case that Phase 1 is successful.

INL will irradiate either at the Energy Innovation Laboratory (EIL) or the Fuels & Applied Science Building (FASB) and analyze using GC (Radiochemistry Laboratory or EIL) and HPLC ESI-MS (EIL). Remaining reagents and remaining irradiated material are to be returned to SHINE Medical.

Original ECP:

SHINE Medical Technologies would like to evaluate the impacts of gamma radiolysis upon a proprietary chelator used in their production radioisotopes for medicinal purposes. This work involves gamma irradiation of aqueous solutions with two chelator

concentrations mostly bound with metal ions and a few without metal ions present. Approximately six different absorbed doses are needed. The maximum absorbed dose required for these experiments is approximately 1000 kGy.

The gamma irradiator located in EIL (REC-688) and FASB (MFC-787) will be used for the gamma irradiations. A small volume of each irradiated sample will be retained by INL for compositional analysis. These analyses will be performed in EIL and RCL (MFC-1702) using gas chromatography and electrospray mass spectrometry. The remaining samples are returned to SHINE.

The proposed period of performance is 09/14/2020 – 01/31/ 2021.

The estimated cost is less than $ 25K. A formal cost estimate is in process.

SECTION C. Environmental Aspects or Potential Sources of Impact:

Air Emissions

There will be very minor emissions from analysis instrumentation. These emissions are covered by existing Air Permitting Applicability Determinations for EIL and RCL.

Discharging to Surface-, Storm-, or Ground Water

N/A

Disturbing Cultural or Biological Resources

FASB is over 50 years old. However, none of the planned activities will impact the structure or aesthetics of the building.

Generating and Managing Waste

The activity will generate industrial waste in the form of PPE and general lab waste. No radiological waste is generated. Unused samples will be returned to SHINE.

Releasing Contaminants

Whenever chemicals are used there is a chance of a spill to the environment (air, water, soil).

Using, Reusing, and Conserving Natural Resources

Material will be diverted from the landfill to the extent possible.

SECTION D. Determine Recommended Level of Environmental Review, Identify Reference(s), and State Justification: Identify the applicable categorical exclusion from 10 Code of Federal Regulation (CFR) 1021, Appendix B, give the appropriate justification, and the approval date.

For Categorical Exclusions (CXs), the proposed action must not: (1) threaten a violation of applicable statutory, regulatory, or permit requirements for environmental, safety, and health, or similar requirements of Department of Energy (DOE) or Executive Orders; (2) require siting and construction or major expansion of waste storage, disposal, recovery, or treatment or facilities; (3) disturb hazardous substances, pollutants, contaminants, or Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)-excluded petroleum and natural gas products that pre-exist in the environment such that there would be uncontrolled or unpermitted releases; (4) have the potential to cause significant impacts on environmentally sensitive resources (see 10 CFR 1021). In addition, no extraordinary circumstances related to the proposal exist that would affect the significance of the action. In addition, the action is not “connected” to other action actions (40 CFR 1508.25(a)(1) and is not related to other actions with individually insignificant but cumulatively significant impacts (40 CFR 1608.27(b)(7)).

References:

10 CFR 1021, Appendix B to subpart D, items B3.6, "Small-scale research and development, laboratory operations, and pilot projects"

Justification:

The proposed R&D activities are consistent with CX B3.6 "Siting, construction, modification, operation, and decommissioning of facilities for small-scale research and development projects; conventional laboratory operations (such as preparation of chemical standards and sample analysis); small-scale pilot projects (generally less than 2 years) frequently conducted to verify a concept before demonstration actions, provided that construction or modification would be within or contiguous to a previously disturbed area (where active utilities and currently used roads are readily accessible). Not included in this category are demonstration actions, meaning actions that are undertaken at a scale to show whether a technology would be viable on a larger scale and suitable for commercial deployment."

Is the project funded by the American Recovery and Reinvestment Act of 2009 (Recovery Act) ☐ Yes ☒ No

Approved by Jason L. Anderson, DOE-ID NEPA Compliance Officer on: 09/08/2022