U. S. DEPARTMENT OF ENERGY
OFFICE OF SCIENCE -- CHICAGO OFFICE

NATIONAL ENVIRONMENTAL POLICY ACT (NEPA)
ENVIRONMENTAL EVALUATION NOTIFICATION FORM

To be completed by "financial assistance award" organization receiving Federal funding. For assistance (including a point of contact), see "Instructions for Preparing SC-CH F-560, Environmental Evaluation Notification Form".

Solicitation/Award No. (if applicable): Request for Isotope Production Proposals 2011

Organization Name: Washington University

Title of Proposed Project/Research: Production of Positron Emitting Radiometals: Cu-64, Y-86, Zr-89

Total DOE Funding/Total Project Funding: 399980

I. Project Description (use additional pages as necessary):

A. Proposed Project/Action (delineate Federally funded/Non-Federally funded portions)

This proposal seeks support to increase our production of yttrium-86 and zirconium-89 production while continuing to produce copper-64. We have the advantage that we already ship out copper-64 to some 12-15 institutions per week (over 60 different institutions total including 2 Canadian sites) and thus our group already has significant experience with producing and shipping radioactive materials. The majority of the funds requested will go towards the purchase of a new hotcell for the production of zirconium-89.
This proposal aims to produce quantities of copper-64, yttrium-86 and zirconium-89 in quantities and schedules suitable for distribution and in support of current and upcoming clinical trials.

B. Would the project proceed without Federal funding? Yes ☐ No ☐

If "yes", describe the impact to the scope:
No

II. Description of Affected Environment:
Laboratory setting with suitable radiation protection and monitoring

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III. Preliminary Questions:

		Yes	No
A.	Is the DOE-funded work *entirely* a "paper study"?	☐	☒
	If "Yes", ensure that the description in Section I reflects this and go directly to Section V.		
B.	Will the work to be performed take place *entirely* in existing buildings?	☒	☐
	*And **NOT**:*		
1.	Threaten a violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health?	☒	☐
2.	Require the siting, construction or major expansion of waste treatment, storage, or disposal facilities?	☒	☐
3.	Disturb hazardous substances, pollutants, or contaminants preexisting in the environment?	☒	☐
4.	Adversely affect environmentally-sensitive resources identified in Section IV.A.?	☒	☐
5.	Be connected to another existing/proposed activity that could potentially create a cumulatively significant impact?	☒	☐
6.	Have an inherent *possibility* for high consequence impacts to human health or the environment (e.g., Biosafety Level 3-4 laboratories, activities involving high levels of radiation)?	☒	☐

If "Yes" to Question III.B. and ALL six subsequent questions, ensure the descriptions in Sections I and II reflect this and go directly to Section V.

IV. Potential Environmental Effects:

Attach/insert an explanation for each "Yes" response.

A. Sensitive Resources: Will the proposed action result in changes and/or disturbances to any of the following resources?

		Yes	No
1.	Threatened/Endangered Species and/or Critical Habitats	☐	☒
2.	Other Protected Species (e.g., Burros, Migratory Birds)	☐	☒
3.	Sensitive Environments (e.g., Tundra/Coral Reefs/Rain Forests)	☐	☒
4.	Archaeological/Historic Resources	☐	☒
5.	Important Farmland	☐	☒
6.	Non-Attainment Areas for Ambient Air Quality Standards	☐	☒
7.	Class I Air Quality Control Region	☐	☒
8.	Special Sources of Groundwater (e.g. Sole Source Aquifer)	☐	☒
9.	Navigable Air Space	☐	☒
10.	Coastal Zones	☐	☒
11.	Areas with Special National Designation (e.g. National Forests, Parks, Trails)	☐	☒
12.	Floodplains and Wetlands	☐	☒

B. Regulated Substances/Activities: Will the proposed action involve any of the following regulated items or activities?

		Yes	No
13.	Natural Resource Damage Assessments	☐	☒
14.	Exotic Organisms	☐	☒
15.	Noxious Weeds	☐	☒
16.	Clearing or Excavation (indicate if greater than one acre)	☐	☒
17.	Dredge or Fill (under Clean Water Act, Section 404, indicate if greater than ten acres)	☐	☒

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B. Regulated Substances/Activities: Will the proposed action involve any of the following regulated items or activities? (continued)

		Yes	No
18.	Noise (in excess of regulations)	☐	☒
19.	Asbestos Removal	☐	☒
20.	PCB's	☐	☒
21.	Import, Manufacture, or Processing of Toxic Substances	☐	☒
22.	Chemical Storage/Use	☐	☒
23.	Pesticide Use	☐	☒
24.	Hazardous, Toxic, or Criteria Pollutant Air Emissions	☐	☒
25.	Liquid Effluents	☐	☒
26.	Underground Injection	☐	☒
27.	Hazardous Waste	☐	☒
28.	Underground Storage Tanks	☐	☒
29.	Radioactive Mixed Waste	☐	☒
30.	Radioactive Waste	☒	☐
31.	Radiation Exposure	☒	☐
32.	Surface Water Protection	☐	☒
33.	Pollution Prevention Act	☐	☒
34.	Ozone Depleting Substances	☐	☒
35.	Off-Road Vehicles	☐	☒
36.	Biosafety Level 3-4 Laboratory	☐	☒

C. Other Relevant Information: Will the proposed action involve the following?

		Yes	No
37.	Potential Violation of Environment, Safety, or Health Regulations/Permits	☐	☒
38.	Siting/Construction/Major Modification of Waste Recovery, or Waste Treatment, Storage, or Disposal Facilities	☐	☒
39.	Disturbance of Pre-existing Contamination	☐	☒
40.	New or Modified Federal/State Permits	☐	☒
41	Public Controversy	☐	☒
42.	Environmental Justice	☐	☒
43.	Action/Involvement of Another Federal Agency (e.g. license, funding, approval)	☒	☐
44.	Action of a State Agency in a State with NEPA-type law. (Does the State Environmental Quality Review Act apply?)	☐	☒
45.	Public Utilities/Services	☐	☒
46.	Depletion of a Non-Renewable Resource	☐	☒
47.	Extraordinary Circumstances	☐	☒
48.	Connected Actions	☐	☒
49.	Exclusively Bench-top Research	☐	☒
50.	Only a Laboratory Setting	☒	☐

V. Financial Assistance Award Organization Concurrence:

A. Organization Official (Name and Title): Dan Szatkowski; Health Physicist

Signature: [signature] Date: 9-17-12

e-mail: szatkowd@wustl.edu Phone: 314 362 3479

B. Optional Concurrence (Name and Title): _____

Signature: _____ Date: _____

e-mail: _____ Phone: _____

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Remainder to be completed by SC-CH

VI. SC-CH Concurrence/Recommendation/Determination:

A. SC-CH Office of Acquisition and Assistance or Office of Safety, Technical & Infrastructure Services:

Project Director or Contract Specialist (Name and Title): Steven Wilson, Grants Management Specialist

Signature: Steven Wilson Date: 9-19-12

B. SC-CH NEPA Team Review:

Is the project/activity appropriate for a determination or a recommendation to the Head of the Field Organization by the NEPA Compliance Officer (NCO) under Subpart D of the DOE NEPA Regulations?

Yes ☒ No ☐

Specific class(es) of action from Appendices A-D to Subpart D (10 CFR 1021): B3.10

Name and Title: _____

Signature: _____ Date: _____

C. SC-CH Counsel (if necessary):

Name and Title: _____

Signature: _____ Date: _____

D. SC-CH NEPA Compliance Officer:

The preceding pages are a record of documentation required under DOE Final NEPA Regulation, 10 CFR 1021.400.

☒ Action may be categorically excluded from further NEPA review. I have determined that the proposed action meets the requirements for Categorical Exclusion referenced above.

☐ Action requires approval by Head of the Field Organization. Recommend preparation of an Environmental Assessment.

☐ Action requires approval by Head of the Field Organization or a Secretarial Officer. Recommend preparation of an Environmental Impact Statement.

Comments/Limitations if necessary:

Signature: Peter R. Siebach Date: 9/20/2012

Peter R. Siebach
SC-CH NEPA Compliance Officer

"Production of Positron Emitting Radiometals: Cu-64, Y-86, Zr-89"

Washington University School of Medicine

Principal Investigator:

Suzanne Lapi. Ph. D.

Use of radioactive substances

Washington University in St. Louis has been producing and distributing non-standard PET radionuclides to the research community for over 10 years. The radionuclides that have been produced include copper-64, bromine-76, gallium-66, yttrium-86, bromine-77, iodine-124 and zirconium-89. Presently, copper-64 is produced on a regular basis and yttrium-86, bromine-76 and zirconium-89 sporadically in lower quantities. The increase in shipping of copper-64 to external institutions is illustrated in Figure 1 and is mainly due to the increasing in clinical trials with this isotope. Since the inception of our automated production system, (October 1, 2008) we have had 145 productions, produced 53562 mCi and shipped out 25629 mCi to external users. It is important to note that **9861 mCi** of this has been produced for human use protocols.

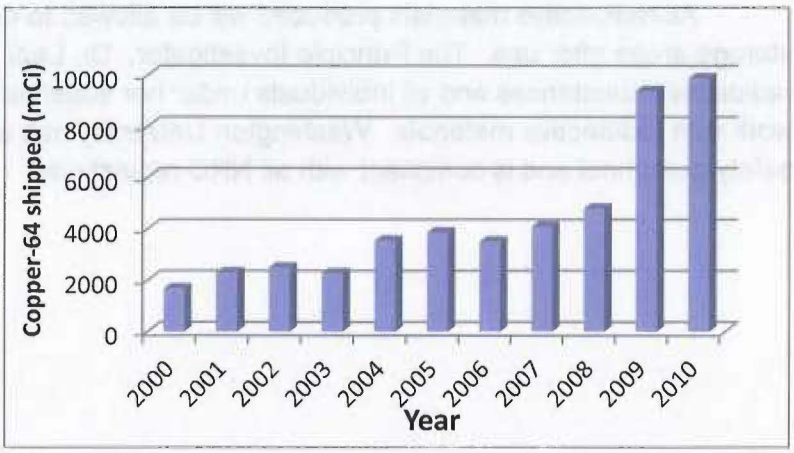

Figure 1. Shipping of copper-64 to outside users from Washington University

This proposal seeks support to increase our production of yttrium-86 and zirconium-89 production while continuing to produce copper-64. We have the advantage that we already ship out copper-64 to some 12-15 institutions per week (over 60 different institutions total including 2 Canadian sites) and thus our group already has significant experience with producing and shipping radioactive materials. A significant portion of the funds requested will go towards the purchase of a new hotcell for the production of zirconium-89.

This proposal aims to produce quantities of copper-64, yttrium-86 and zirconium-89 in quantities and schedules suitable for distribution and in support of current and upcoming clinical trials.

All proton irradiations will be carried out using the Washington University CS-15 (Cyclotron Corporation, Ep = 15 MeV) shown below in Figure 2.

Figure 2. Washington University CS-15 Cyclotron

All radioactive materials produced will be allowed to decay in appropriate shielded storage areas after use. The Principle Investigator, Dr. Lapi, is an authorized user of radioactive substances and all individuals under her supervision have the necessary training to work with radioactive materials. Washington University has an excellent team of radiation safety personnel and is compliant with all NRC regulations.