

U. S. DEPARTMENT OF ENERGY, OFFICE OF SCIENCE  
INTEGRATED SUPPORT CENTER—CHICAGO OFFICE

NATIONAL ENVIRONMENTAL POLICY ACT (NEPA)  
ENVIRONMENTAL EVALUATION NOTIFICATION FORM

To be completed by "Applicant," i.e., organization receiving funds and/or implementing Federal Actions as defined by 40 CFR § 1508.18. For assistance, refer to "Instructions for Preparing ISC-CH F-560, Environmental Evaluation Notification Form."

Solicitation/Award No. (if applicable): DE-FOA-0001099 Research, Development and Training in Isotope Production

Organization Name: Sloan Kettering Institute for Cancer Research

Title of Proposed Action: Production of the Medically Important Radionuclides 52Mn and 90Nb

Total DOE Funding/Total Funding: \$279,946

I. Project Description: (Use explanation pages if additional space is required)

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

This collaborative proposal will create an integrated program of radionuclide production and research activities aimed toward the efficient isolation and characterization of the medically-relevant nuclides 52Mn and 90Nb. These two metallo-radionuclides were selected based on their emerging importance to the nuclide and medical communities but general lack of availability. The research described in this proposal will develop parameters and procedures for delivering clinical-grade, high specific-activity 52Mn and 90Nb for preclinical and translational applications by optimizing the cyclotron targetry and separation chemistry of 52Mn and 90Nb for use in basic positron-emission tomography (PET) radiotracer experiments. In addition the infrastructure that will be put in place through this project will enable a long term research partnership, with broader impact, between the three participating institutions.

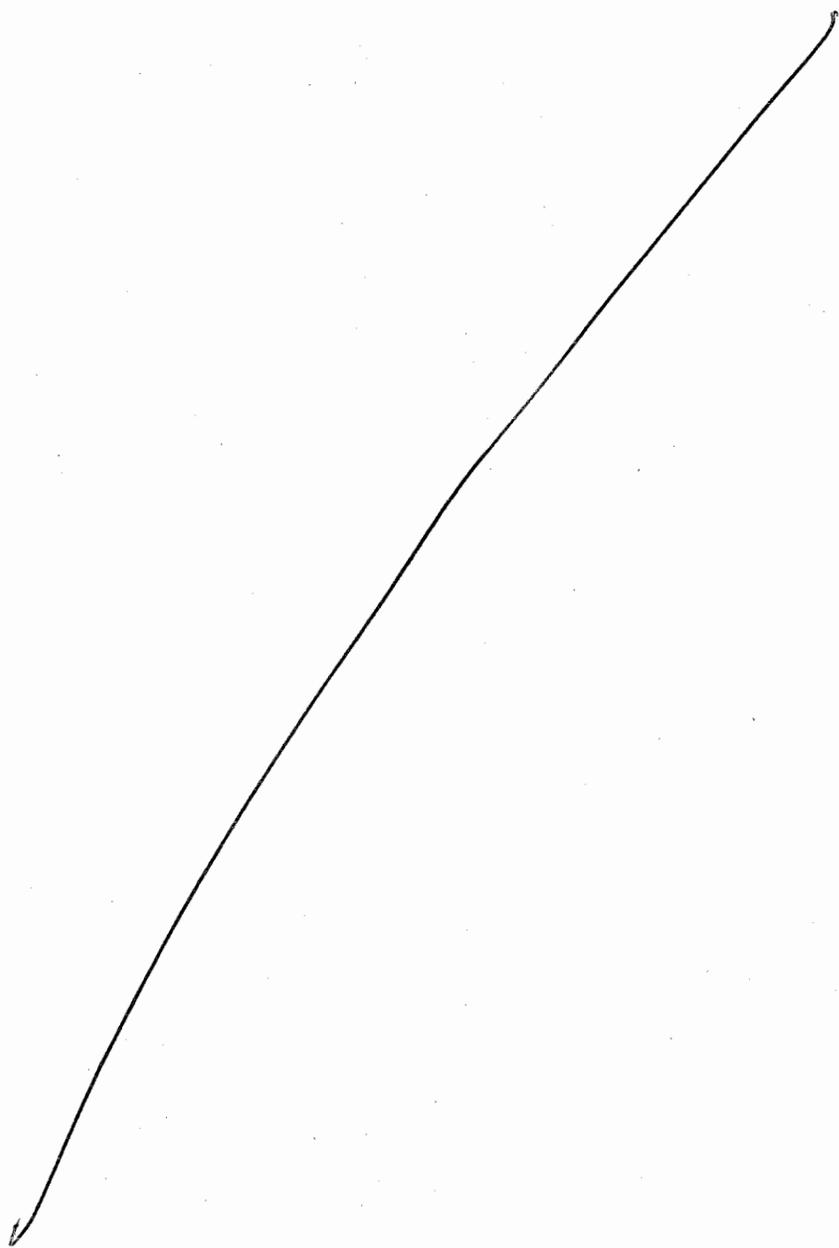
B. Would the project proceed without Federal funding?

Yes  No

If "yes," use explanation page.

II. Description of Affected Environment: (Use explanation pages if additional space is required)

The work will be conducted indoors in the RMIP CORE laboratories within MSKCC - these areas include include Rms SC-08, 634 and 734 in the Schwartz Building and include multiple shielded radiochemistry cells and fume hoods, general chemistry lab-benches. work will also be done in our new Central Isotope Laboratory with 2 Hotcells & 1 Minicell; laminar flow hoods; QC lab; cell labeling lab; antibody labeling facilities. In November 2013 a new GEMS PETtrace-10 cyclotron was installed in Memorial Hospital with QC and labeling equipment, ancillary hotcells/minicells and GMP production facilities to increase MSKs basic science and clinical translation programs with PET nuclides - including those listed under this proposal. Additional radiochemistry space is housed in the Mortimer B. Zuckerman Research Center (ZRC) across the street from the above laboratories. All personnel in proximity to the study will be fully trained, monitored and approved radiation workers.



III. Preliminary Questions:

- |   | Yes                      | No                                  |
|---|--------------------------|-------------------------------------|
| A. <u>Is the DOE-funded work routinely administrative or <i>entirely</i> advisory or a "paper study?"</u> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

***If "Yes", ensure that the description in Section I reflects this and go directly to Section V.***

- B. Is there any potential whatsoever for: (Provide an explanation for each "Yes" response)

- |  |                          |                                     |
|--|--------------------------|-------------------------------------|
| 1. Work to be performed outdoors?  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 2. Major modification of a building interior?  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 3. Threat of violation of applicable statutory, regulatory, or permit requirements for environment, safety, and health?        | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 4. Siting, construction or major expansion of waste treatment, storage, or disposal facilities?                                | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5. Disturbance to hazardous substances, pollutants, or contaminants preexisting in the environment?                            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6. The presence of any environmentally-sensitive resources?  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7. Potential for high consequence impacts to human health or the environment?  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8. The work being connected to another existing/proposed activity that could potentially create a significant impact?          | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 9. Nearby past, present, and/or reasonably foreseeable future actions such that collectively significant impacts could result? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 10. Scientific or public controversy, uncertainty over potential impacts, or conflicts regarding resource usage?               | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

***If "No" to ALL Section III.B. questions, go directly to Section V.***

IV. Potential Environmental Effects: (Provide an explanation for each "Yes" response)

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

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

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

- |  |                          |                                     |
|--|--------------------------|-------------------------------------|
| 13. Natural Resource Damage Assessments  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 14. Invasive Species or Exotic Organisms                                       | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 15. Noxious Weeds  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 16. Clearing or Excavation (indicate if greater than one acre)                 | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 17. Dredge or Fill (under Clean Water Act, Section 404, greater than one acre) | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

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

	Yes	No
18. Noise (in excess of regulations)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
19. Asbestos Removal	<input type="checkbox"/>	<input checked="" type="checkbox"/>
20. Polychlorinated biphenyls (PCBs)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
21. Import, Manufacture, or Processing of Toxic Substances	<input type="checkbox"/>	<input checked="" type="checkbox"/>
22. Chemical Storage/Use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
23. Pesticide Use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
24. Hazardous, Toxic, or Criteria Pollutant Air Emissions	<input type="checkbox"/>	<input checked="" type="checkbox"/>
25. Liquid Effluents	<input type="checkbox"/>	<input checked="" type="checkbox"/>
26. Spill Prevention/Surface Water Protection	<input type="checkbox"/>	<input checked="" type="checkbox"/>
27. Underground Injection	<input type="checkbox"/>	<input checked="" type="checkbox"/>
28. Hazardous Waste	<input type="checkbox"/>	<input checked="" type="checkbox"/>
29. Underground Storage Tanks	<input type="checkbox"/>	<input checked="" type="checkbox"/>
30. Radioactive or Radioactive Mixed Waste	<input checked="" type="checkbox"/>	<input type="checkbox"/>
31. Radiation Exposure	<input checked="" type="checkbox"/>	<input type="checkbox"/>
32. Nanoscale Materials	<input type="checkbox"/>	<input checked="" type="checkbox"/>
33. Genetically Engineered Microorganisms/Plants or Synthetic Biology?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
34. Ozone Depleting Substances	<input type="checkbox"/>	<input checked="" type="checkbox"/>
35. Greenhouse Gas Generation/Sustainability	<input type="checkbox"/>	<input checked="" type="checkbox"/>
36. Off-Road Vehicles	<input type="checkbox"/>	<input checked="" type="checkbox"/>
37. Biosafety Level 3-4 Laboratory	<input type="checkbox"/>	<input checked="" type="checkbox"/>
38. Research on Human Subjects or other Vertebrate Animals	<input type="checkbox"/>	<input checked="" type="checkbox"/>
39. Facility footprint exceeds 5,000 Square Feet	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

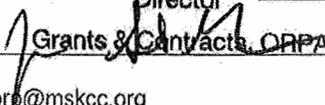
	Yes	No
40. Disproportionate Nearby Presence of Minority and/or Low Income Populations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
41. Existing, Modified, or New Federal/State Permits	<input type="checkbox"/>	<input checked="" type="checkbox"/>
42. Involvement of Another Federal Agency (e.g. license/permit, funding, approval)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
43. Action in a State with NEPA-type law	<input type="checkbox"/>	<input checked="" type="checkbox"/>
44. Expansion of Public Utilities/Services	<input type="checkbox"/>	<input checked="" type="checkbox"/>
45. Depletion of a Non-Renewable Resources	<input type="checkbox"/>	<input checked="" type="checkbox"/>
46. Subject to an Existing Institutional Work Planning and Control Process	<input type="checkbox"/>	<input checked="" type="checkbox"/>
47. Other Pertinent Information Which Could Impact Human Health or the Environment	<input type="checkbox"/>	<input checked="" type="checkbox"/>

V. Applicant Certification that to the best of their knowledge all information provided on this form is accurate:

Does this disclosure contain classified, confidential, or other exempt information that DOE would not be obligated to disclose pursuant to the Freedom of Information Act? Yes  No

**Jason St. Germain**

A. Organization Official (Name and Title): Annmarie L. Pacchia- PhD, VP, Research & Project Admin.

Signature:  Grants & Contracts, ORPA Date: 8/11/16

e-mail: sponsor@mskcc.org Phone: 646-227-3273

B. Optional Secondary Approval (Name and Title): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

e-mail: \_\_\_\_\_ Phone: \_\_\_\_\_

Remainder to be completed by DOE

VI. DOE Concurrence/Recommendation/Determination:

A. DOE Project Director/Program Manager or Contract/Grant Management Specialist:

Has the Applicant completed the Form correctly?

Yes

No

Does an existing Generic Categorical Exclusion apply?

If yes, indicate:

Name and Title: Thy H. Nguyen, Grants Management Specialist

Signature: \_\_\_\_\_

Date: 9/12/16

B. DOE NEPA Team Review:

Is the class of action identified in the DOE NEPA Regulations (Appendices A-D to Subpart D (10 CFR § 1021))?

Yes

No

If yes, specify the class(es) of action: B3.12, B3.6, B3.10

Name and Title: Peter Siebach, NCO

Signature: \_\_\_\_\_

Date: 9/12/2016

C. DOE Counsel (if requested):

Name and Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

D. DOE 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 any:

NEPA Compliance Officer:

Name: Peter R. Siebach

Signature: \_\_\_\_\_

Date: 9/12/2016



Optional Additional Narrative: (add additional detail to description to Sections I and II or explanations to responses in Sections III and IV.



To Whom It May Concern:

In my absence, Jason St Germain, Director, Grants and Contracts will sign grants and related documents as an institutional official for Sloan-Kettering Institute for Cancer Research.

A handwritten signature in cursive script, which appears to read "Annmarie L. Pacchia". The signature is written in black ink and is positioned above the printed name.

Annmarie L. Pacchia, PhD., Vice President  
Office of Research & Project Administration

