UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

June 1, 2017

Raquel C. Bono, MC, USN
Director Defense Health Agency
DHHQ / Attn: Vice Admiral Bono
7700 Arlington Bouelvard, Suite #5101
Falls Church, Virginia 22042-5101

SUBJECT: DEFENSE HEALTH AGENCY, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 594592

Dear Admiral Bono:

This is in reference to your application dated April 10, 2017, requesting NRC License No. 45-35423-01. In order to continue our review, we need the following additional information:

1. Section 8.5, "Radioactive Material" of NUREG 1556 Vol. 9 provides information that applicants should include in their license application for requested material.
    a. The 35.400 brachytherapy source Model PD-103 SL and SH manufactured by Mills Biopharmaceuticals are no longer in the SSDR. Additionally, the models I125 SL and SH are now manufactured by Core Oncology, Inc. Please revise your request accordingly.
    b. Please note that the SSDR for the Theragenics Model 200 Pd-130 sealed sources has a maximum activity of 100 mCi. Please revise your request or confirm that you will only possess sources that are within the SSDR maximum amounts.
    c. With regard to your request for Y-90 SIR-spheres, the SSDR lists the activity per vial to be 296 mCi. Please indicate if you want your possession limit revised to reflect the maximum activity per vial.
    d. Please confirm that there will be no 35.500 materials used, or provide a description of all sources and/or devices that will be used.
    e. There are currently isotopes listed on the Navy permits you provided in your application that you have not requested in your application; i.e. Xenon-133, Radium-223 and Uranyl Nitrate. Please revise your request to include these items or indicate the disposition of them.
    f. With regard to your request for depleted uranium, for its use you listed shielding of teletherapy and blood irradiators. Please revise your requested use or provide information on the teletherapy and blood irradiators that you intend to possess.

2. Section 8.8, "Recordkeeping for Decommissioning and Financial Assurance" of NUREG 1556 Vol. 9 provides information regarding financial assurance. On page 3 of your application you make a statement that your possession of material is estimated and anticipated to remain below the possession limits that might require financial assurance for decommissioning. Please confirm that you will maintain your possession limits below the limits requiring financial assurance or provide financial assurance in accordance with 10 CFR 30.35.

3. Section 8.11, "Radiation Safety Officer" of NUREG 1556 Vol. 9 provides information regarding the Radiation Safety Officer requirements. Please confirm that you will comply with the requirements of 10 CFR 35.24 or provide an explanation why the DHA is unable to provide the required notification as per 10 CFR 35.14(b); note the notification is within 30 days after the designation of a temporary RSO.

4. Section 8.13, "Authorized Nuclear Pharmacist" of NUREG 1556 Vol. 9 lists requirements for designating ANPs. 10 CFR 32.72(b)(2) requires specific training for authorized nuclear pharmacists and for experienced nuclear pharmacists. Please confirm that the minimum training and experience criteria you will use to grant authorization for nuclear pharmacists will be equivalent to that described in 10 CFR 32.72(b)(2) and/or (4).

5. Section 8.14, "Authorized Medical Physicist" of NUREG 1556 Vol. 9 lists requirements for authorizing AMPs. On page 9 of your application you make references to several sections of 10 CFR Part 35; i.e. 10 CFR 35.961, 10 CFR 35.961(c), and 10 CR 35.972. 10 CFR Part 35 does not contain these references. Please revise and submit the paragraph with the proper references.

6. Section 8.16, "Facility Diagram" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relevant to facility diagrams. Please provide the following:
    a. On your diagram for Building 9, there is an area labelled, "Response and Advisory RAMT Storage area." This room was not included in the summary page of authorized use areas. Please confirm if you intend to add this.
    b. On your building diagrams for WRNMMC and METC, you did not include what areas are immediately above or below the authorized rooms. Please provide this information.
    c. Describe the methods to ensure that whenever the HDR is not in use or is unattended the console keys will be inaccessible to unauthorized persons.
    d. Sufficient detail in the PET facility diagram to indicate locations of shielding and/or shielding equipment (e.g., hot cells for positron-emitting radionuclides), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety, such as remote handling equipment and area monitors.
    e. Shielding calculations, with information about the type, thickness and density of all shielding materials, including walls, floor, ceiling, and viewing ports to enable independent verification of shielding calculations for all PET and therapy facilities. For HDR facilities, include information on the maximum "on time" per hour and per week and occupancy factors used for all adjacent areas. Additionally, include the location and dimensions of any portable shields used for treatments. Shielding calculations must demonstrate compliance with the limits specified in 10 CFR 20.1301.
    f. The location of the isocenter or center of the source(s), the directions of primary beam usage for teletherapy units and, in the case of an isocentric teletherapy unit, the plane of beam rotation. For a remote afterloader, the position of the source used in calculations should simulate worst case source position during patient treatment.
    g. With respect to the drawing for the HDR facility in WRNMMC Building 19, provide the location of area radiation monitoring equipment that indicates the presence of radiation to an individual entering the treatment room.
    h. Other radiation producing equipment housed within the same or adjacent rooms (e.g., linear accelerator, orthovoltage machine).

7. Section 8.17, "Radiation Monitoring Instruments" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relevant to radiation monitoring instruments. On page 14 of your application you provided a list of the types of instruments that you possess. Specify the number of radiation detection instruments that you have available at each site and include the range for each type of instrument (milliroentgens per hour or counts per minute). Appendix M of NUREG-1556, Volume 7 addresses radiation monitoring instrument specifications and may be helpful in developing your response.

8. Section 8.19, "Therapy Unit – Calibration and Use" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relevant to therapy units.
    a. Please confirm that if spot-check (HDR Daily QA) results indicate the malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
    b. Indicate who is authorized to perform the HDR Daily QA.

9. Section 8.20, "Other Equipment/Facilities" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relevant to specialized facility equipment.
    a. Describe the warning systems (i.e. signs, warning lights, and alarms) deployed in each therapy room.
    b. Provide methods to ensure correct placement of portable shields used for treatments with remote afterloaders, if applicable.

10. Section 8.22, "Safety Procedures and Instructions" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relevant to safety procedures and instructions.
    a. Please confirm that therapy device operators, authorized users, and authorized medical physicists receive the vendor training for use of the device.
    b. Confirm that the names and telephone numbers of the AUs, the AMPs, and the RSO will be posted at the console of the HDR unit in the event it operates abnormally.

11. Section 8.24, "Area Surveys" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relative to survey requirements. Page 22 of your application you stated that infrequent use areas can be surveyed monthly.
    a. Confirm that you will comply with 10 CFR 35.70 requiring a survey each day that unsealed radionuclides are use.
    b. Confirm that WRNMMC building 19, designated for monthly surveys, does not utilize unsealed radionuclides.

12. Section 8.27, "Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources" of NUREG 1556 Vol. 9 provides guidance on information to include with applications relative to vendor services for therapy equipment.
    a. 10 CFR 35.605 requires that only a person specifically licensed by the NRC or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit. In support of your request to authorize the Varian Service representative, to perform these activities, please submit:
        i. the types of activities requested;
        ii. a description of the training and experience demonstrating that the proposed employee is qualified for these uses; and

iii. a copy of the manufacturer's training certification and an outline of the training in the procedures to be followed.

b. Confirm that all scheduled service recommended by the manufacturer will be performed in accordance with the manufacturer's instructions.

13. Please note that NUREG 1556 Vol. 11 was revised in February 2017. Please confirm that the following Appendices, as referenced in your application, will be changed:
    a. Facilities and Equipment – refer to Appendix E in Rev. 1
    b. Safety Procedures – refer to Appendix O in Rev. 1
    c. Area Surveys – refer to Appendix L in Rev. 1
    d. Leak Tests – refer to Appendix M in Rev. 1
    e. Reporting – refer to Appendix Y of Rev. 1

14. Section 8.5.2,"Financial Assurance and Recordkeeping for Decommissioning" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to recordkeeping for decommissioning. State the following: "Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and /or 10 CFR 70.51(a)(3), prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) to the appropriate NRC Regional Office."

15. Section 8.7, "Individuals Responsible for Radiation Safety Program and their Training and Experience" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to management oversight. Since you have requested to consolidate WRNMMC, FBCH and METC into a broad scope license, to adequately consider such a request, the NRC will require additional specific information for review. Please provide documentation of an administrative structure, organization, and procedures adequate to ensure safe operation by users at all facilities under a single radiation safety program as follows:
    a. Provide a written delegation of authority to the RSO signed by senior management. This statement should include provisions for the RSO to carry out his/her authority over each site's program without redirection or hindrance by site management. Include in the statement the RSO's authority to terminate unsafe practices and activities jeopardizing the safety or workers, the public, or environment.
    b. Provide assurance that the RSO has sufficient time to perform duties, appropriate staff support, and provision for RSO absence.
    c. Confirm that senior management will conduct site tours and meetings with site management and the RSO. Please state the minimum frequency of site visits by the RSO for the purpose of monitoring (e.g. facility/site surveys and review of reports and records for each site) and feedback to site personnel, as well as support staff, to ensure that daily operations at each site include radiation safety activities, approved procedures, safe practices, and compliance with regulations and licensing conditions.
    d. Describe the mechanisms for alerting the RSO and responding to unsafe practices and urgent situations that may occur at any site. Please describe the mechanisms for reporting to and informing management of unsafe practices and incidents, and the management role in responding to such circumstances.

e. Describe your methods and checks designed to ensure that the RSO possesses and reviews current regulations.
f. Describe the chain of authority for ensuring compliance with regulatory requirements.
g. Confirm that senior management has an active role in sharing program responsibilities with the RSO. Please state the minimum frequency of reports from the RSO to senior management and meetings with senior management and the RSO.
h. Confirm that senior management reviews and is involved with program audits and evaluations. Please describe the periodic, interactive (i.e., with feedback) program audits at each site, indicating audit frequency and reporting commensurate with site operations. Identify the individuals who will conduct the audits and describe their training and experience.
i. Describe how you will coordinate inventory control of licensed material among sites with the intended focus of continually monitoring types and quantities of material, thereby ensuring that regulatory possession limits are not exceeded.

16. Section 8.7.2, "Radiation Safety Committee" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to their RSC. Please provide the following:
    a. Criteria used for selecting members of the RSC, including what members and the number of members constituting a quorum (specify that a subject matter expert must be present for discussions of that area). Members should be indicated by position title, rather than by name. Identify the Radiation Safety Committee Chairperson. Provide documentation on their training and experience involving licensed materials and identify their position in your organization. Do **NOT** submit a curriculum vitae for each member;
    b. Criteria and procedure describing the approval process used by the RSC and RSO for authorizing new users and new uses, including research personnel;
    c. A description of the duties and responsibilities of the RSC, including:
        i. review and approval of permitted program and procedural changes prior to implementation
        ii. implementation of program and procedural changes
        iii. audit of licensed operations to determine compliance
        iv. appropriate actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence; and
        v. a description of the process for procedure and program review and approval, including documentation of the specific change (At a minimum, documentation should state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.)
    d. Provide a sample authorized use permit.
    e. Confirm that the Radiation Safety Manual is submitted as part of your license application, and that any changes in the Manual information and procedures shall be submitted to the NRC and approved by amendment of your license prior to implementing the changes. Alternatively, you may submit the Radiation Safety Manual as a reference for specific procedures referred to in Items of your license application; in this case only changes made in the referenced procedures would require amendment of the license. You may also minimize the need for frequent amendments if you specify those sections of your manual which are administrative in nature and/or do not reduce the level of safety. Such

areas might include: modifications required by NRC rule changes; revision of internal management forms; selection of authorized contractors for dosimetry, waste disposal, calibration, and other similar services; references to specific manufacturers and/or models of equipment.

f. In Tab 3 page 7, you stated that the RSO may provide interim authorizations. In order for the Radiation Safety Officer to perform interim authorizations, your Radiation Safety Committee must develop and approve the criteria for granting interim approvals. The Radiation Safety Committee must review and confirm these approvals at their next regular meeting. Please provide the specific criteria that your Radiation Safety Committee has developed for interim approvals. This criteria should address the following:
   i. The minimum training requirements for users of the materials and the uses specified for interim authorization.
   ii. The types of radioactive materials and maximum possession limits for interim authorization.
   iii. The types of uses which can be approved for interim authorization. These should include only routine procedures that are typically performed by other authorized users at your facility, and for which no extraordinary safety precautions are required.
   iv. The minimum facility, equipment, and safety requirements for the uses which may be approved for interim authorization.

g. Submit a description of the Radiation Safety Committee program for review of permits issued to authorized users and uses for renewal or re-issue of the permits, and state the frequency at which this review will be required. The program for renewal of permits should include a review of the authorized users' safety and compliance history, types and quantities of materials requested, facilities and equipment, and training and supervision of radiation workers in the users' laboratory.

h. 10 CFR 35.6 states, in part, "A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research." Please indicate whether research involving human subjects and byproduct material at your institution is conducted, funded, supported or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. If this is not the case, you must provide the following information for our review and approval:
   i. the type of research, isotope(s), chemical/physical form and activity.
   ii. the sponsor(s) of the research.
   iii. identification of the appropriate reviewing and approving committees (e.g., Institutional Review Board and Radiation Safety Committee);

   Additionally, regardless of whether or not research involving human subjects and byproduct material at your institution is conducted, funded, supported or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects, 10 CFR 35.6 requires that at a minimum, prior review and approval of the research activities by an Institutional Review Board and informed consent from the human subjects be obtained. Please confirm the following will be obtained prior to performing research on human subjects:

iv. review and approval of the research activity by an Institutional Review Board; and
v. informed consent from each research subject.

17. Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to worker training. Confirm that the lesson plans for all the worker groups provided by WRNMMC are applicable to FBCH and METC.

18. Section 8.9, "Facilities and Equipment" and Appendix E of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to use areas.
    a. Describe the criteria the RSC or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). The description will need to include the method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme that take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems—including pertinent airflow rates, pressures, filtration equipment, and monitoring systems. For facilities and equipment used in special applications, such as those described above, the application will include their locations (i.e., buildings and room numbers) and special considerations that the RSC or RSO (or both) will use in authorizing byproduct material use. Also describe the procedures for control, review, and approval of significant facilities or equipment modifications.
    b. Describe the laboratory equipment used when working with volatile radioactive materials. Confirm that you will be using a fume hood and specify if a filter will be used. Specify the minimum face velocity on the fume hood and the frequency that the face velocity will be measured.

19. Section 8.10, "Radiation Safety Program" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to their radiation safety program.
    a. 10 CFR 33.13 and 33.14 require applicants to establish administrative controls and provisions relating to management review necessary to ensure safe operations. 10 CFR 20.1101(c) requires that the licensee review the radiation protection program content and implementation at least annually. Regulatory Guide 10.5, Second Proposed Revision 2 (DG-0005) recommends that an audit and appraisal program be part of the management review. Provide the following information regarding the management review program:
        i. Describe the senior management oversight of your radiation safety program. Specify the mechanisms that will be used by senior management to ensure that they are aware of the NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.
        ii. Confirm that the Radiation Safety Committee performs an audit of the overall radiation safety program, the Radiation Safety Officer performance, and the radiation staff performance at least annually, and that the results of the audit will be reported to senior management.

b. Specify the types and frequencies of audits that will be implemented by the Radiation Safety Officer and staff to determine user compliance with the requirements of the NRC license, your radiation safety program, and the users' Radiation Safety Committee permit. These audits should include such topics as: reviews of users' inventory and survey records, evaluation of users' training through observation and discussion, and performance of independent work area surveys.
c. Specify the types and frequencies of surveys and monitoring that will be performed by the Radiation Safety Officer and staff. Confirm that surveys will include both unrestricted and restricted areas. The survey frequency may be based on a hazard scheme such as that found in NUREG 1556 Vol. 11 Appendix L.

20. Section 8.10.2, "Radiation Monitoring Instruments" of NUREG 1556 Vol 11 provides guidance on information to include with applications relative to radiation monitoring instruments. Your application included an authorized use of material for instrument calibrations. Please provide the following:
    a. Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor licensed by the NRC or an Agreement State to perform instrument calibrations. Licensees that want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix H of this NUREG.
    b. Your application did not specify the instrument used in your bioassay program for determining activity in the thyroid. Please specify your instrumentation and calibration procedures, including the type of phantom you will use.

21. Section 8.10.3, "Material Receipt and Accountability" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to the accounting of licensed material.
    a. Describe your procedures to ensure that all procurement of licensed material and all use of licensed material are properly authorized by the license and approved by your Radiation Safety Committee. Describe your procedures for ordering and receipt of licensed materials, and for notification of responsible persons upon the receipt of these materials.
    b. Provide the following statement: "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."
    c. Describe the administrative controls and provisions related to materials control, accounting. Describe the method for maintaining accountability of licensed material at all times.
    d. Submit your procedures for transfer and transportation of licensed material between authorized users at your facilities, and your procedures for transfer and transportation of licensed material to other licensees. Describe your program to control such transfers, including update of material inventory and audits of users' procedures.

22. Section 8.10.4, "Occupational Dose" of NUREG 1556 Vol. 11 provides guidance on information to include with applications relative to the evaluation of occupational dose. Specify your criteria for performing internal monitoring which may be required for certain uses of material under your license. Submit a description of procedures, including the methods and instrumentation to be used for sampling and analysis,

calibration of equipment, the lower limit of detection for the method and instrumentation, and the action levels for each radionuclide.

23. On page 4 of your application you indicate that the authorized use for materials A and B includes animal studies. Appendix H of NUREG-1556, Volume 7 addresses considerations for laboratory animal uses. If licensed materials are to be used in animals, please submit:
    a. a description of the animal housing facilities,
    b. a description of the training that will be provided to individuals caring for animals containing licensed materials, and
    c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

24. Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-spheres Licensing Guidance, Revision 9 dated February 12, 2016, provides guidance on information to include with applications regarding use of microspheres. Please provide a commitment that you will use this guidance in the development of your microsphere program. Additionally, commit to following the guidance provided on the NRC's website for any other 35.1000 activities that you may authorize in the future.

We will continue our review upon receipt of this information. Please reply to my attention at:

Robin L. Elliott
Mail Control No. 594592
USNRC, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
King of Prussia, PA 19406

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

Robin Elliott

Robin Elliott, Health Physicist
Medical Branch
Division of Nuclear Materials Safety
Region I

License No. 45-35423-01
Docket No. 030-39046
Mail Control No. 594592

cc: LTC H. Michael Stewart, Jr.,
Radiation Safety Officer