March 22, 2011

MEMORANDUM TO: Thomas G. Hiltz, Chief
Advanced Fuel Cycle, Enrichment
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Division of Fuel Cycle Safety
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Office of Nuclear Material Safety
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FROM: Maria C. Guardiola, Chemical Engineer ***/RA/***
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SUBJECT: MEETING WITH SHINE MEDICAL TECHNOLOGIES ON PRELIMINARY DISCUSSION REGARDING LETTER OF INTENT

On Monday, March 7, 2011, the staff met with representatives from SHINE (Subcritical Hybrid Intense Neutron Emitter) Medical Technologies at the U.S. Nuclear Regulatory Commission's (NRC's) headquarters. The purpose of the meeting was to hold a preliminary discussion between NRC staff and SHINE representatives regarding non-proprietary aspects of the SHINE technology and facility, and topical areas where SHINE representatives would like to gain a better understanding of NRC's process.

After the welcome and introductions, Ms. Adams gave a brief explanation of the purpose and scope of the meeting. She handed the meeting over to SHINE representative, Dr. Vann Bynum. He proceeded to give a SHINE introduction technology presentation. SHINE members were presented and their collaborating partners were mentioned.

Dr. Vann Bynum continued to explain the isotope production assembly. He stated that the SHINE isotope production facility will be able to cover about 50 percent of the US supply and communicated the key benefits of their design. The proposed technology will use an accelerator to create primary neutrons. These, in turn, enter a low-enriched uranium solution.

Dr. Vann Bynum gave an overview of the physical and operational concepts of the SHINE Driver. SHINE is still looking for options as to the disposition of the waste that will be created.

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Mr. Voth from the Office of Nuclear Reactor Regulation (NRR) asked what will be the isotope of focus. SHINE responded that their focus will be Molybdenum-99 (Mo-99). Mr. Font, also from NRR, asked if their intention was to go directly to the pharmacies with the Mo-99 product. SHINE said that those were not their intentions at this point. Their current customer is a generator manufacturer, and they have no intention of applying for the production of additional isotopes at this point.

Afterwards, the discussion focused on topical areas for which SHINE was seeking guidance.

I. 10 CFR Part 50 Applicability

Mr. Freels expressed that SHINE may be interested in applying for a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50.2 exemption from the definition of Production Facility. Lisa London from the Office of the General Counsel (OGC) said that NRC would need at least six months to review a request for this exemption and that the exemption may or may not be granted. She also informed SHINE that if they petitioned for rulemaking to revise the production facility definition that would require at least 14 months, and such petition may or may not be granted. Additionally, she explained that should SHINE license their production facility under Part 50 all other aspects of the license (e.g., accelerator radiation safety, Part 30 and Part 70 licenses) would be under the Part 50 license as long as they occurred within the confines of the Part 50 facility. Thus, NRC would retain regulatory authority over the entire production facility; and SHINE would not have to deal with regulation by two agencies (though it was pointed out that the agreement state would still have regulatory authority over byproduct that exits the facility).

II. 10 CFR Part 70 Subpart H Applicability

Mr. Freels asked whether the proposed facility would fall under 10 CFR Part 70 if they were granted an exemption from 10 CFR Part 50. SHINE also asked for some clarification on the definition of enriched uranium processing. The NRC staff cannot make a final determination without additional details.

III. 10 CFR Part 51 Applicability

Mr. Freels wanted to know how long the NRC needs to decide whether an Environmental Impact Statement (EIS) or Environmental Assessment/Finding of No Significant Impact (EA/FONSI) will be required. Mr. Imboden, from NRR, said a simple EA/FONSI takes about 6 months to develop, a complex EA/FONSI takes about 1 year and an EIS takes a minimum of 18 months; barring hearings. The NRC will not be able to make a determination on whether an EA or EIS is required until the application (including an Environmental Report) is submitted and reviewed by NRC staff. Mr. Freels added that SHINE would impose a freeze point beyond which SHINE would not change the design in any way that would have an impact on the license or the National Environmental Policy Act review.

Mr. Michael Tschiltz asked how SHINE would deal with the waste streams. Dr. Vann Bynum from SHINE referenced the draft legislation that addresses waste via a uranium lease and take-back provision. Mr. Jim Shaffner, from the Office of Federal and State Materials and Environmental Management Programs, inquired about Class B and C waste. Mr. Voth from NRR asked about the difference between Babcox & Wilcox's (B&W) Aqueous Homo-geneous Reactor waste and SHINE's waste. Mr. Freels replied that while the composition of the two

waste streams are the same, by definition B&W's waste is high-level waste and SHINE's waste is not.

Mr. Tschiltz asked why would SHINE think it might not need an Environmental Report; Mr. Freels mentioned that 10 CFR Part 51.60(b)(1) through (b)(4) might exempt SHINE from doing an Environmental Report. Mr. Hiltz believes if SHINE is licensed under 10 CFR Part 70, then it is likely to come under the provision of "any other action" in 10 CFR Part 51.60(b)(5).

IV. Restricted Data

SHINE wants to know if any of their information would be considered restricted data. Mr. Bernard Stapleton from the Office of Nuclear Security and Incident Response said that the Department of Energy (DOE) would make that determination, not the NRC. The inquiry has been forwarded to the DOE, and it should be a matter of weeks before the NRC receives a response.

V. Regulatory Review Framework

If the SHINE license application would fall under 10 CFR Part 50, NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," augmented with interim staff guidance which is under development, would be the guidance document.

VI. Material Control and Accounting (MC&A)

Mr. Pham said the NRC needs to know the specific amount of nuclear material they will be handling to determine what category the facility will be. Based on what the NRC staff knows, if the facility were to fall under 10 CFR Part 70, it would be a Category II facility. SHINE would use NUREG-1065 "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities," and consider 10 CFR Parts 74.41, 74.43 and 74.45. If it would fall under 10 CFR Part 50, the NRC would need to think about how to handle MC&A for SHINE. Physical protection must also be considered; and Mr. Sapountzis advised SHINE to use Regulatory Guide 5.69, "Guidance for the Applications of the Radiological Sabotage Design-Basis Threat in the Design, Development, and Implementation of a Physical Security Program," and 10 CFR 73.

VI. Agreement State Responsibility

Mrs. Rodgers asked if they are preparing an Emergency Plan. Mr. Freels said they are working on an Emergency Plan that will comply with local fire regulations. At this point, they still do not know how much Mo-99 will be on site at any one time.

Members of the public had no questions or comments.

Enclosures:
1. Attendees List
2. SHINE Presentation Slides

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