Report of Meeting Held to Discuss Existing and Future Radionuclide Requirements for the National Cancer Institute

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Executive Summary

This report is a synopsis of the discussions and conclusions of an expert panel convened to assist the NCI in determining and prioritizing its immediate and future requirements for imaging and therapeutic radionuclides and identifying means by which these needs might be efficiently met. The expert panel members (listed in the appendix) met on Friday, February 22, 2008, at Tower II Conference Center, Science Applications International Corporation (SAIC), 1710 SAIC Drive, McLean, VA.

NCI's Immediate and Future Needs

The panel identified significant needs for high specific activity therapeutic and imaging radionuclides for research and clinical trials.

The four radionuclides for which there is an immediate and compelling need are: ^{211}Astatine; ^{213}Bismuth, ^{223}Radium and ^{225}Actinium.

Meeting NCI's Needs

Short-term:

- The existing cyclotron at the clinical center and its cGMP hot cell (NIH campus in Bethesda, MD) should be utilized more efficiently.
- A consortium of two or three existing cyclotron facilities should be formed to provide the necessary (GMP) clinical-grade radionuclides in a timely manner.
- Consider means to get access to Copper 67.

In the longer term, the NCI should consider, in cooperation with the Department of Energy (DOE), the construction and operation of a dedicated multi-particle cyclotron for the production of radionuclides for research and clinical trials. However, since approximately 90 percent of all radionuclides can be produced in a 30-MeV cyclotron, at this time it is unclear whether this should be a 30-MeV or a 70-MeV facility. Owing to this lack of clarity and its cost implications (the cost estimate for a new 70-MeV facility with cGMP hot cells would likely be above $50M), the panel recommended that the NCI delay this decision and revisit it once the short term recommendations have been implemented. At the most recent meeting at ARRONAX, the cost of their facility had increased to 40M euros. A better estimate of the current cost of building a 70-MeV facility capable of making GMP clinical grade material, therefore, needs to be generated and compared to the cost of a 30-MeV facility so the incremental cost can be examined in the context of the extra functionality.

Increase interest in the training of physicians in nuclear medicine, form/stimulate advocacy group(s) for the delivery of radiation therapy and increase training and availability of radiochemists for the production of radioisotopes.

Introduction

Much of the science for production of the next generation of targeted radio-pharmaceuticals has been demonstrated. Basic chemical advances in labeling molecules at high levels of radioactivity have allowed assessment of the therapeutic potential of alpha-emitting radionuclides in preclinical models and in human patients. The range of alpha particles in tissues is only a few cell diameters, offering the potential of pairing cell-specific molecular targeting with radiation of a comparable range of action. This predicted localized cytotoxicity of alpha particles has been demonstrated, providing compelling evidence for initiating clinical trials with antibodies radiolabeled with alpha-emitting radionuclides for leukemia and brain tumors [1]. At least eleven beta-emitting radionuclides (^{177}Lutetium, ^{166}Holmium, ^{186}Rhenium, ^{188}Rhenium, ^{67}Copper, ^{149}Promethium, ^{199}Gold, ^{77}Bromine, and ^{105}Rhodium, ^{90}Yttrium and ^{131}Iodine) and four alpha-emitting radionuclides (^{213}Bismuth, ^{223}Radium, ^{225}Actinium, and ^{211}Astatine) are involved in current preclinical and clinical research. However, a shortage of radionuclides for research and clinical trials continues to impede the full implementation of targeted radiopharmaceutical therapeutics. Of the radionuclides mentioned above, only two (^{90}Yttrium and ^{131}Iodine) are readily available in a form suitable for use in clinical trials [2]. Targeted radioisotopes have been proven effective for the treatment of certain commonly occurring forms of cancer. Lymphoma experts have noted that beta-emitting radioimmunotherapy compounds represent the most active single agents ever developed for the treatment of indolent B-cell lymphoma [2]. Currently, there are only two commercially available radiopharmaceuticals, ^{90}Yttrium ibritumomab tiuxetan (Zevalin®, FDA-approved in 2002) and ^{131}Iodine tositumomab (Bexxar®, FDA-approved in 2003), both of which have had impressive clinical responses showing that a single cycle of treatment with either of these can result in essentially the same level of tumor response as multiple cycles of conventional chemotherapy [3], generally with a fraction of the toxicity (Fig 1). These drugs display excellent clinical results, on the order of 60 percent to 80 percent overall response and 20 percent to 40 percent complete response rates for patients with relapsed, recurrent, or refractory indolent B-cell lymphoma [4-7].

NCI's Immediate Radioisotope Requirements

Presently, the majority of production of clinical-grade therapeutic radionuclides is limited to reactor-produced beta-emitting radionuclides (e.g., ^{90}Yttrium and ^{131}Iodine). There is an immediate and acute need for alpha-emitting therapeutic radionuclides, which have higher linear energy transfer (LET) (around 100 keV/μm) and shorter range of action, resulting in far more selective and localized cytotoxicity (Fig 2). Besides alpha-emitters, additional beta-emitters are needed to enhance theragnostics (compounds that contain an isotope or isotopes that enable both imaging and therapy) for improved determination of the radiation dose.

Table 1 provides a list of the expert panel's recommendations for radionuclides of interest, including the particle energies and production mechanisms. The NCI has a specific and unique interest in these radionuclides, as they cannot initiate clinical trials involving certain of the recommended isotopes because they are not consistently available in sufficient amounts or with adequate quality (e.g., purity and specific activity). In addition, in the past, NCI has approved research grants involving novel

radionuclides, but has been forced to discontinue the grants due to limited availability of radionuclides. Demand is also outpacing limited supply for paired isotopes for theragnostics; i.e., therapeutic/PET imaging radionuclides, such as $^{67}Cu/^{64}Cu$, $^{90}Y/^{86}Y$ and $^{131}I/^{124}I$.

Table 1: Requested therapeutic radionuclides and their production mechanisms [8]

Radionuclide	Emission	Half-life (hrs)	Production Mechanism	Particle Energy (MeV)
^{211}At	α	7.2	$^{210}Bi(\alpha,2n)$	E_α (30)
^{67}Cu	β	62	$^{68}Zn(p, 2p)$	E_p (>> 30)
			$^{70}Zn(p,\alpha)$	E_p (>> 30)
			$^{67}Zn(n,p)$	Reactor
^{77}Br	β	57	$^{75}As(\alpha,xn)$	E_α (40–15)
			$^{nat}Se(p,xn)$	E_p (20–2)
			$^{79}Br(p,3n)$	E_p(50–30)
^{225}Ac	α	240	Thorium 229 generator Ion exchange from ^{225}Ra	Reactor
			$^{226}Ra(p,2n)$	E_p (25–8)

Presently, only three cyclotrons have demonstrated the capability to produce ^{211}Astatine (Table 2). Most of the requested therapeutic radionuclides can be produced in a 30-MeV cyclotron, with the exception of ^{67}Cu, which requires a higher-energy accelerator (>70 MeV) for maximal production, though a low-energy channel exists for this purpose.

Table 2: Cyclotrons that are capable of producing ^{211}At

Site	Cyclotron	Installation Date
Duke University	CS-30	1985
University of Washington	Scanditronix	1983
NIH Clinical Center	CS-30	1985
University of Pennsylvania	JSW 30	1985

Trace Life Sciences in Denton, Texas, currently produces ^{67}Cu but at suboptimal energy parameters. All of the cyclotrons that can produce ^{211}At are older designs, lack cGMP hot cells, and do not have adequate facilities to support a training program. The primary

operation at Duke University is for the production of reimbursed positron emission tomography (PET) imaging agents. The Duke University Radiology Department has not expressed interest in supporting other users, but with additional funding and support, it may be possible to change this perspective. The Clinical Center/NIH CS-30 cyclotron and associated cGMP hot cell (installed in 1985) is underutilized and could be a valuable resource if managed more efficiently. The Penn cyclotron is currently over-committed and hence unable to produce ^{211}At but has been developing a program for eventual routine production. The University of Washington cyclotron currently produces ^{211}At for a preclinical research program.

Scenarios for Improved Radionuclide Availability

The panel discussed possible scenarios for improving the availability of the requested radionuclides:

- A "virtual" production network utilizing existing manufacturing capacity
- A newly constructed production facility

1. "Virtual" Production Network for Requested Radionuclides

The panel agreed that a small-scale (two–four cyclotron centers) production network would likely be the most efficient short-term solution to the present radionuclide shortage. A small number of existing centers could utilize a distribution network or be partnered with a distribution specialist to provide radionuclides throughout the country. An integral component of this approach would be the use of the existing NIH cyclotron and its associated cGMP hot cells. The 2–3 centers could be backed up by a larger network of cyclotrons to provide material for processing in a central facility during beam downtime. Panel members noted that the beam time of existing cyclotrons is only being used at approximately 15 percent to 20 percent of capacity. However, there are a variety of conditions (including funding mechanisms and access to cGMP hot cells) that cause this to occur and will need to be addressed to implement this approach.

A larger distributed production network was rejected as a long-term solution for several reasons. Although several existing facilities have excess beam time, many do not have cGMP capabilities. They also cannot provide sufficient reliability, sufficient radionuclide-specific activity or quality control, and are unable to scale up their facilities to assist in a production network, or to align with patient studies performed at other sites. There are also significant FDA regulatory barriers to multi-center production, and it is difficult to monitor many different sites to ensure they are producing the same cGMP quality material (e.g., radionuclide-specific activity and pharmaceutical-grade parameters).

2. National Radionuclide/Radiochemistry Facility

The panel discussed in some detail the feasibility of constructing a new NCI National Cyclotron Radionuclide/Radiochemistry facility. The panel discussed cyclotron technical parameters, operation business models, approximate cost to build and operate the national cyclotron, and its location. An overview of these discussions follows.

Beam Energy and Technical Specification – 70-MeV vs. 30-MeV

Approximately 90 percent of all radionuclides for use in nuclear medicine therapeutic/imaging studies can be produced using a 30-MeV cyclotron. There was a consensus among the panel that a 30-MeV (proton)/30-MeV (alpha) beam cyclotron would be most advantageous. The benefits of a higher-energy (70-MeV) beam were also considered and thought to be of interest to DOE and its programs related to radiation effects and low-energy nuclear physics. The panel noted that the 70-MeV cyclotron being constructed in Nantes (France) will be operational by the end of 2008. Ion Beam Applications (IBA) is apparently no longer considering the construction of a 30-MeV (proton)/30-MeV (alpha) cyclotron in southern California for commercial reasons but IBA might be open to doing this if it were as a joint venture with NCI/DOE. It was noted that NCI presently has a cooperative agreement with IBA.

The panel discussed several facility design scenarios, including: radionuclide production and the needs for concrete shielding that rise with the energy of the beam; a cGMP radiopharmacy, including air-handling transport tubes for transport of radionuclides between the cyclotron and radiopharmacy/radiochemistry laboratories; a radiochemistry lab for research development; training and educational facility; and offices with parking. Dr. David Schyler (BNL) provided the chapter "Examples of Cyclotron Facilities" from his International Atomic Energy Agency draft technical document for this discussion.

The future cost of a fully operational 70-MeV cyclotron with attendant GMP clinical-grade production facilities is likely to be over $50M. The latest (April 2008) estimate of the cost of the Nantes facility is 40M euros. The incremental savings for utilizing lower-beam energy (30-MeV) were not known at the meeting, but would result from lower cost for the cyclotron, less concrete shielding for the irradiation vaults, smaller access doors to the vaults, and operational savings.

Proposed Business Model and List of Functions

The facility as envisioned before would include a core facility that is centrally funded with operating costs paid on a cost-recovery basis and grants for specialized work. Industry could buy beam time and/or beam lines, as presently implemented for other energy sources at various DOE national laboratories (for example, access to X-ray beam lines at the Advanced Photon Source, some of which NIH funded). Industry could be involved in building these beam lines and possibly pay rent.

Location

Due to the short half-lives of some radionuclides, location and proximity to an airport and distribution center (e.g., FedEx or DHL) may be important. Two sites (e.g., one on each coast) may be necessary to service the entire country. Proximity to comprehensive cancer care centers (especially those interested in diagnostic imaging or radionuclide therapy) conducting clinical trials is also of importance. Other considerations include the proximity of academic institutions, commercial centers, and the locations of existing and planned cyclotrons. It is expected that a Public–Private Partnership partner, if one were found, would likely influence the location decision.

Partnership with the Department of Energy (DOE) or Other Agencies/Nanotech

The expert panel agreed that a partnership between DOE and NCI would be beneficial. A major issue is that the radionuclides used in nuclear medicine make up a very small percentage of DOE-produced nuclides. The cost of operation if the facility were located at a national lab would be much higher than if located at a university or funded by a public–private partnership. The panel noted that DOE has been constrained in the past from providing material certified for projects that involve human research. In addition, Public Law 101-101, which stipulates that DOE recover the full cost for radionuclide production, whether for clinical or basic research, could potentially interfere with an NCI–DOE partnership. This law was modified in the 103rd Congress but still retains some limitations on supporting research with radionuclides. Given these circumstances, NCI should consider contacting other agencies (e.g., NIH institutes, DHS, DOD, and the USDA), in addition to the DOE and keep the partnership open to all interested parties.

Potential Way Forward Using the FFRDC

In the short term, NCI can make efforts to bring users together with providers and/or subsidize the costs of current commercially available radionuclides toward the objective of providing a dependable supply of radionuclides for use in NCI-sponsored clinical studies. This could be accomplished through the following steps:

1. Improve the overall operation of the NIH Clinical Center cyclotron facility. Task it with providing ^{211}At and evaluate production of ^{225}Ac and ^{77}Br for clinical trials.
2. Develop an acquisition strategy to access the existing infrastructure of 30-MeV cyclotrons to generate a steady and reliable source of ^{211}At, ^{225}Ac, and ^{77}Br.
    a. NCI-Frederick, through its Federally Funded Research and Development Center (FFRDC) Contractor, SAIC-Frederick, Inc., and the DOE, could issue a solicitation to organization(s) (identified by the committee), indicating NCI's interest in acquiring access to a steady supply of radionuclides for NCI-sponsored clinical trials. There would be the opportunity to offer economic incentives for access to off-hour cyclotron use (labor, materials, facility, etc., and reimburse the organizations for the costs associated with producing materials for NCI).
    b. A cyclotron production network consisting of 2–4 cyclotrons could be developed for radionuclide supply.
    c. NCI, through its FFRDC Contractor and the DOE, could offer to assist in upgrading an existing facility for enhanced availability of the proposed radionuclides. For example, this might involve funding to enhance cGMP hot cell resources at existing production facilities.
    d. A solicitation for a reliable supply of ^{67}Cu for all of NCI's intramural and extramural clinical requirements could be issued.

We anticipate that the implementation of these short-term action items will meet NCI's immediate needs for radionuclides for conducting clinical trials. The data generated from these activities should further demonstrate the efficacy of therapeutic radionuclides, and this information can then be used to better determine the need for an additional dedicated

cyclotron. This information is likely to become available in the next three to five years. If NCI is interested in pursuing a centrally located National Radionuclide/Radiopharmaceutical Facility, it should obtain copies of the five DOE National Biomedical Tracer Facility (NBTF) proposals and query the various DOE National Laboratories and accelerator manufacturers (IBA, Advanced Cyclotron Systems, formerly EBCO, Scanditronix, etc.) as to production costs, operating costs, and all associated costs for production and research for imaging and therapeutic radionuclides for the next generation.

Other Issues Affecting Utilization of Therapeutic Radionuclides

In addition to the issues of radionuclide availability discussed above, the panel members raised additional issues that need to be incorporated into a comprehensive solution.

Training

It was unanimously agreed that there are shortages of qualified candidate practitioners at every level of the practice of nuclear medicine: nuclear medicine technologists, radiopharmaceutical researchers and manufacturers, radiochemists, medical physicists (radiation dose calculations), and clinicians (image interpretation and administration of the radionuclide therapy). More information on shortages of qualified practitioners in the nuclear medicine workforce is detailed in Chapter 8 of *Advancing Nuclear Medicine Through Innovation* (Natl. Academies Press) [2].

The NCI is in a position to facilitate training in nuclear medicine, but this would have to be focused at a facility. This should occur immediately, and new state-of-the-art training facilities should be built into any new cyclotron complex. There were some discussions of whether this training would be restricted to postgraduates or could include a graduate-level program. The feasibility of a graduate program likely depends on the location of the facility. Another specific type of training discussed was an alternative to the physician certification process. The expense and time requirements of the current system (Nuclear Regulatory Commission requirements) may be limiting the applicant pool (i.e., training of radiation oncologists for use of unsealed sources).

Advocacy

Advocacy for adequate CMS (Centers for Medicare and Medicaid Services) reimbursement of radioimmunotherapy and in-favor of prescription practice were discussed and recognized as important to prevent the underutilization of radiopharmaceuticals. The lay public must be educated to generate demand for these promising therapies. Currently, many hospitals do not have radiation (unsealed source) facilities (rooms), trained staff, etc., which effectively prevents them from administering radionuclide therapy. Many doctors who are not certified to administer such therapy (unsealed sources) do not prescribe it out of fear of losing their patients/income. It was stated that NCI's efforts should include a significant advocacy component.

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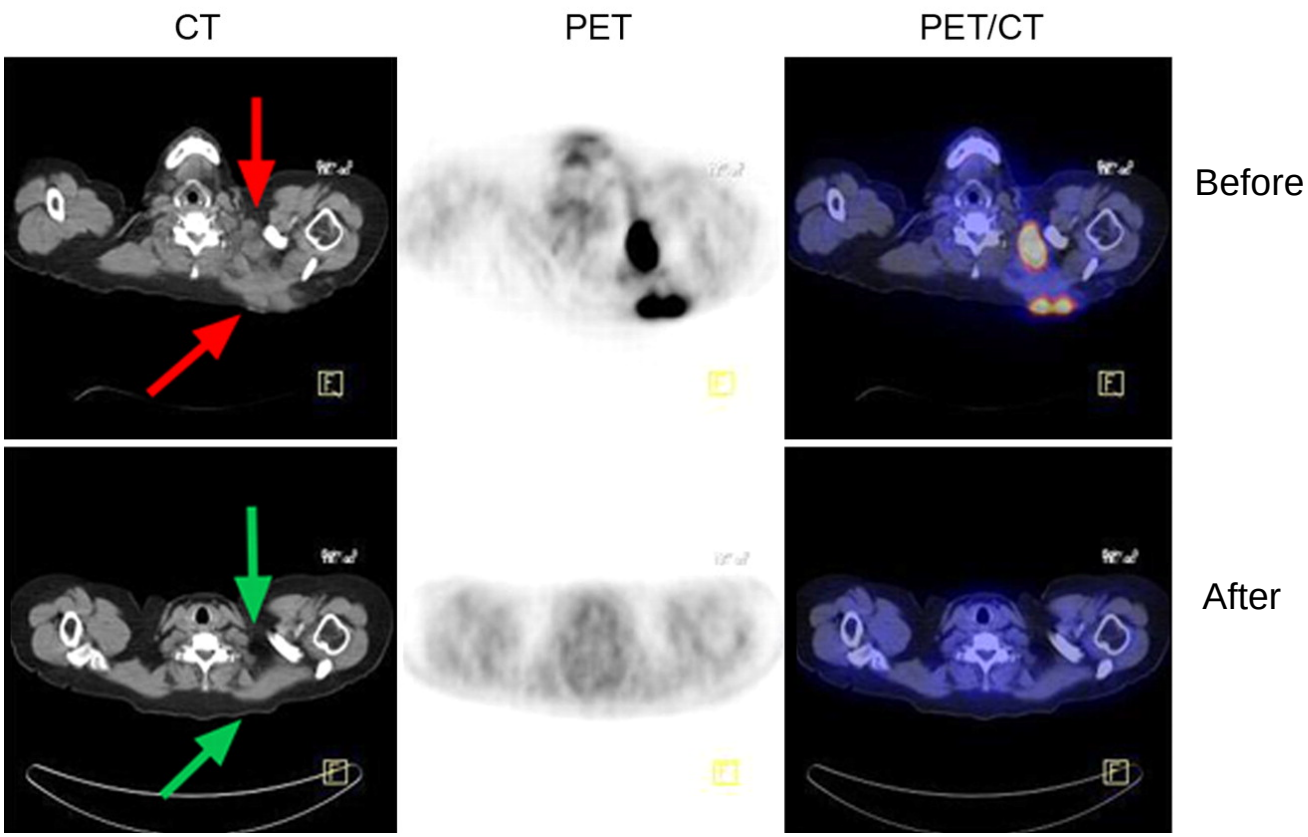

Figure 1. Radionuclides are demonstrated effective cancer therapies.
^{90}Y–ibritumomab tiuxetan *(Zevalin)* therapy evaluated by transverse computed tomography (CT), positron emission tomography (PET), and fused PET/CT images before and after treatment. Hypermetabolic masses are labeled (red arrows) on the before-treatment images. After ^{90}Y–ibritumomab tiuxetan treatment, no masses are visible in areas of previous disease (green arrows). Reproduced with permission of Peter Conti, University of Southern California, Los Angeles.

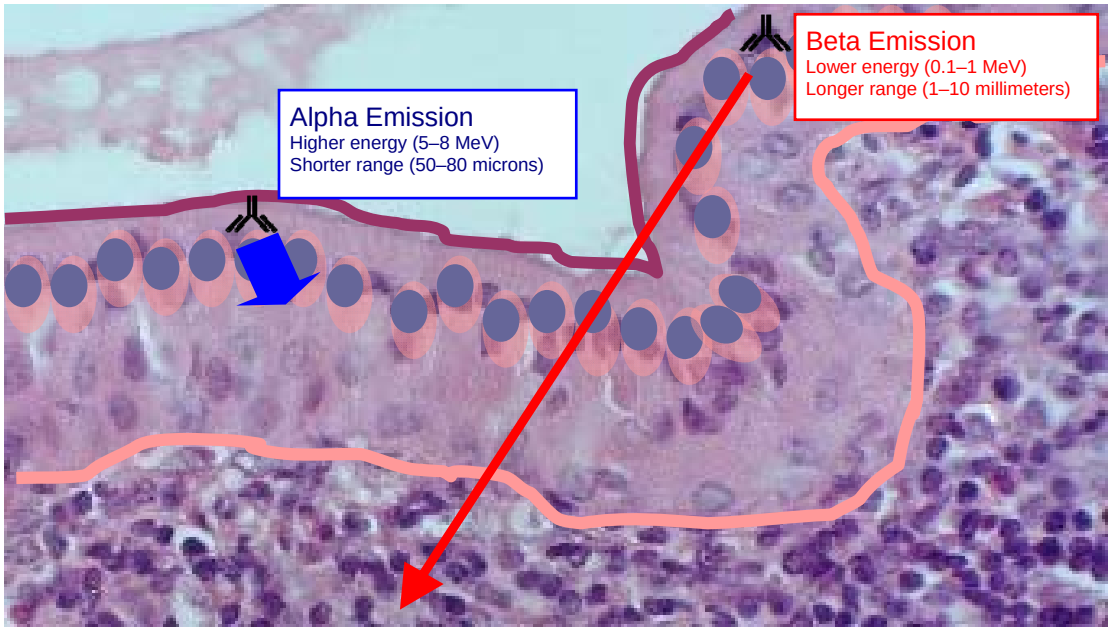

Figure 2. Penetration of alpha and beta particles in tissue. Alpha particles are higher energy (usually 5‑8 MeV) and shorter range (usually 50–80 microns—just a few cell diameters). Beta particles are lower energy (usually 0.1–1 MeV) and longer range (usually 1–10 millimeters). Values are taken from *Advancing Nuclear Medicine Through Innovation* (Natl. Academies Press). The higher energy and shorter range of alpha-emitters gives them their localized potent cytotoxicity.

APPENDIX

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