MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

August 10, 2016

**MEETING SUMMARY**

## PURPOSE

To discuss the draft report of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Germanium-68/Gallium-68 (Ge-68/Ga-68) Generators Subcommittee.

## OUTCOME

The ACMUI Ge-68/Ga-68 Generator Licensing Guidance Sub-Committee provided their draft report for discussion with the full Committee. Subcommittee members included: Dr. Pat Zanzonico (Chair), Mr. Frank Costello, Dr. Sue Langhorst, Dr. Darlene Metter, and Dr. Christopher Palestro. During the meeting, the Committee unanimously approved the draft report. The ACMUI made recommendations on revisions to the draft Ge-68/Ga-68 Generators Licensing Guidance and the NRC staff gained a better understanding of the views and opinions of the ACMUI for further consideration by the NRC.

Full transcripts and handouts from the ACMUI meeting can be found on NRC's public website: http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/

The draft and final ACMUI Ge-68/Ga-68 Generators Subcommittee reports are available on NRC's public website under "ACMUI Subcommittee Reports": http://www.nrc.gov/reading-rm/doc-collections/acmui/reports/

## AGENDA TOPIC

Discuss the ACMUI Ge-68/Ga-68 Generator Licensing Guidance Subcommittee report.

## RECOMMENDATIONS AND ACTIONS

The Ge-68/Ga-68 Generators Subcommittee discussed the following major recommendations in their report:

1. The subcommittee recommended that the section entitled, "Licensing Guidance," on page 4 of the report, be re-named, "Purpose," and re-located to the beginning of the Guidance (i.e., immediately following the Table of Contents). An explicit statement such as the following should be included, "This Guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of a column based Ge-68/Ga-68 generator for producing Ga-68 to be used in the preparation of Ga-68 radiopharmaceuticals."

2. The subcommittee recommended clarification of what is regulated under 10 CFR 35.200 and 10 CFR 35.1000, on pages 5-6 of the report. The guidance should state that the regulation of Ga-68 radiopharmaceuticals under 10 CFR 35.200 applies to patient dosages obtained from appropriately trained authorized users or authorized nuclear

pharmacists within a medical facility as well as from commercial nuclear pharmacies. Accordingly, the subcommittee recommended revisions of the passage in lines 73-84 on page 2 of the Licensing Guidance, including the section entitled, "Commercial Nuclear Pharmacy User under 10 CFR 30.33," as follows:

**Use of Ga-68 Radiopharmaceuticals**

Please note that licensees that use unit dosages of Ga-68 radiopharmaceuticals for medical imaging and localization studies will be regulated under 10 CFR 35.200 and authorized users (AUs) must comply with the requirements of 10 CFR 35.290. The licensee may use a Ga-68 radiopharmaceutical that is prepared from the elution of a Ge-68/Ga-68 generator for medical use for imaging and localization studies that is either:

1) Obtained in a manner described in 10 CFR 35.200 (c) or (d);

2) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements and has made commitments as described in this guidance; or,

3) Prepared by an authorized nuclear pharmacist (ANP); a physician who is an AU who meets the requirements of this license guidance and the requirements specified in 10 CFR 35.290, or 10 CFR 35.390 and 10 CFR 35.290(c)(1)(ii)(G); or an individual under the supervision, as specified in 10 CFR 35.27, of the ANP or the physician who is an AU and have made commitments as described in this guidance.

Licensees that use cyclotron-produced Ga-68 radiopharmaceuticals for medical imaging and localization studies will be regulated under 10 CFR 35.200 and AUs must meet 10 CFR 35.290.

3. The subcommittee recommended modifying the language in the "Use of Ge-68/Ga-68 Generators" Section, on page 6 of the report, to the following language:

**Use of Ge-68/Ga-68 Generators**

Recently, the FDA approved a gallium-68 (Ga-68) radiopharmaceutical for diagnostic imaging of somatostatin receptor (SSR)-positive neuroendocrine tumors. Ga-68 is a positron emitter which allows Ga-68 radiopharmaceuticals to be imaged using positron emission tomography (PET) in a manner similar to fluorine-18 (F-18) radiopharmaceuticals. Ga-68 produced in a cyclotron, like F-18, may be used to produce Ga-68 radiopharmaceuticals for use under 10 CFR 35.200. However, unlike F-18, Ga-68 can also be produced from the elution of a Ge-68/Ga-68 generator to prepare Ga-68 radiopharmaceuticals. As such, the Ge-68/Ga-68 generator eluate generally cannot be used directly in patients for imaging, but only as a precursor for the preparation of Ga-68-labeled radiopharmaceuticals.

4. The subcommittee recommended modifying the language in the "Authorized Individuals" Section, on page 7 of the report, to the following language:

4) Meets the criteria under 10 CFR 35.290, "Training for imaging and localization studies;"

AND

5) Has completed the following training in the use of a Ge-68/Ga-68 generator for producing Ga-68 radiopharmaceuticals for 35.200 use:

a. elution and quality control procedures needed to determine Ga-68 activity and Ge-68 breakthrough levels appropriate for the preparation of radiopharmaceuticals for imaging and localization studies;
b. measuring and testing the eluate for radionuclidic purity; and
c. safety procedures for the use of the Ge-68/Ga-68 generator.

5. The subcommittee recommended modifying the language in the "Training for individuals other than AUs and ANPs" Section, on page 8 of the report, to the following language:

**Training for individuals others than AUs and ANPs**

The applicant shall commit to provide training in the licensee's procedures to all individuals involved in Ge-68/Ga-68 generator use for the production of Ga-68 radiopharmaceuticals for 35.200 use, commensurate with the individual's duties to be performed. This training must be provided to all individuals eluting the generator or preparing, or measuring the Ga-68 unit dose.

6. The subcommittee recommended modifying the language in the "Radiation Protection Program Changes" Section, on page 8 of the report, to the following language:

This guidance may be revised as additional experience is gained regarding the use of a Ge-68/Ga-68 generator for preparation of Ga-68 radiopharmaceuticals for 35.200 use. An applicant initially applying for authorization for use of Ge-68/Ga-68 generator under this 35.1000 use may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes without the need to amend the license to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

The Draft Comments on the Draft Germanium-68/Gallium-68 Generators Licensing Guidance Subcommittee Report (ML16209A215) was unanimously approved by the full ACMUI. The Final Comments on the Draft Germanium-68/Gallium-68 Generators Licensing Guidance Report (ML16238A311) is posted on the ACMUI Subcommittee Report Webpage.

Attachments:

1. List of Attendees
2. Agenda

**MLXXXXXXXXX**

| **OFC** | MSTR/MSEB | MSTR/MSEB | MSTR/MSEB |
|---|---|---|---|
| **NAME** | M. Smethers | M. Fuller | D. Bollock |
| **DATE** | 09/1/2016 | 09/1/2016 | / /2016 |

Attachment 1

## MEETING ATTENDEES

### ACMUI

| | |
|---|---|
| Pat B. Zanzonico, Ph.D. | Vice Chairman |
| Francis M. Costello | Member |
| Vasken Dilsizian, M.D. | Member |
| Susan M. Langhorst, Ph.D. | Member |
| Darlene F. Metter, M.D. | Member |
| Michael D. O'Hara, Ph.D. | Member |
| Christopher J. Palestro, M.D. | Member |
| John H. Suh, M.D. | Member |
| Laura M. Weil | Member |
| *Richard Green* | *Non-Voting Member* |

### NRC

| | |
|---|---|
| Michael Fuller | Leader, Medical Radiation Safety Team and Designated Federal Officer |
| Sophie Holiday | ACMUI Coordinator and Alternate Designated Federal Officer |
| Jennifer Bishop | RIII |
| Colleen Casey | RIII |
| Jackie Cook | RIV |
| Said Daibes, Ph.D. | NMSS |
| Christina England | OGC |
| Sara Forster | RIII |
| Cassandra Frazier | RIII |
| Adam Gendelman | OGC |
| John Giessner | RIII |
| Vincent Holahan, Ph.D. | NMSS |
| Donna-Beth Howe, Ph.D. | NMSS |
| Penny Lanzisera | RI |
| Johari Moore | OCM |
| Janice Nguyen | RI |
| Dennis O'Dowd | RIII |
| Patty Pelke | RIII |
| Toye Simmons | RIII |
| Gretchen Rivera-Capella | NMSS |
| Michelle Smethers | NMSS |
| Katie Tapp, Ph.D. | NMSS |

Attachment 1

**MEMBERS OF THE PUBLIC**

| | |
|---|---|
| Andrew Brown | The Ohio State University Wexner Medical Center |
| Steve Chilinski | PharmaLogic |
| Cason Coan | Alabama Department of Public Health |
| James Cook | Advanced Accelerator Applications |
| Hendrik Engelbrecht | unaffiliated |
| Lynne Fairobent | American Association of Physicists in Medicine (AAPM) |
| Sandra Gabriel | International Atomic Energy Agency (IAEA) |
| Wendy Galbraith | University of Oklahoma College of Pharmacy |
| Dan Hill | Cardinal Health |
| Akram Hussein | The Ohio State University Wexner Medical Center |
| Thomas Huston | Veterans Health Administration National Health Physics Program (VANHPP) |
| Brandon Juran | Minnesota Department of Health |
| Scott Knishka | University of Wisconsin School of Pharmacy |
| Caitlin Kubler | Society of Nuclear Medicine and Molecular Imaging |
| Samuel Leveritt | Cardinal Health |
| Ralph Lieto | St. Joseph Health |
| Richard Martin | American Association of Physicists in Medicine (AAPM) |
| Steven Mattmuller | Kettering Health |
| Neil Petry | Duke University Medical Center |
| Andrea Ravard | Cedar Sinai Medical Center |
| Michael Sheetz | University of Pittsburgh |
| Jared Thompson | Arkansas Department of Health |
| Cindy Tomlinson | American Society for Radiation Oncology (ASTRO) |
| Richard Van Sant | PharmaLogic |
| Joseph Wissing | Veterans Health Administration National Health Physics Program (VANHPP) |
| Melonie Wissing | Veterans Health Administration National Health Physics Program (VANHPP) |

Attachment 2

**Advisory Committee on the Medical Uses of Isotopes**
**TELECONFERENCE AGENDA**
**Wednesday, August 10, 2016**
**1:30 PM – 3:30 PM (ET)**

**OPEN SESSION**

**1:30 –3:30 pm**
Discuss the Draft ACMUI Germanium-68/Gallium-68 Generators Licensing Guidance Subcommittee Report