2019 Current Fiscal Year Report: Advisory Committee on the Medical Uses of Isotopes

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1. Department or Agency	2. Fiscal Year
Nuclear Regulatory Commission	2019
3. Committee or Subcommittee	**3b. GSA Committee No.**
Advisory Committee on the Medical Uses of Isotopes	1102

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/01/2018	03/01/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No	42 U.S.C. 2201	

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue		Not Applicable

11. Establishment Authority Agency Authority

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 U.S.C. 2201	07/01/1958	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports 6

16b. Report Date	Report Title
01/31/2019	Nursing Mother Guidelines for the Medical Administration of Radionuclides, Final Report (Table Revised)
02/27/2019	Training and Experience for All Modalities Subcommittee, Final Report (35.390)
04/10/2019	Subcommittee on the ACMUI Bylaws, Final Report
05/06/2019	Germanium-68/Gallium-68 Generator Licensing Guidance, Revision 1, Final Report
05/09/2019	Yttrium-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance, Revision 10, Final Report
06/19/2019	Draft Proposed Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," Revision 1 (Phase 1), Final Report

Number of Committee Reports Listed: 6

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 3 **Other Activities** 0 **17d. Total** 5

Meetings and Dates

Purpose	Start	End

To discuss the ACMUI Training and Experience (T&E) Draft Subcommittee Report regarding the requirements for authorized users under Title 10 Code of Federal Regulations (10 CFR) 35.300, “Use of unsealed byproduct material for which a written directive is required.”	02/26/2019 - 02/26/2019
To discuss issues related to the implementation of the medical regulations in Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material."	04/03/2019 - 04/04/2019
To Discuss (1) the revised 2019 Advisory Committee on the Medical Uses of Isotopes (ACMUI) Bylaws and (2) the ACMUI Regulatory Guide 8.39, “Release of Patients Administered Radioactive Material” Draft Subcommittee Report	06/10/2019 - 06/10/2019
To Discuss (1) the NRC’s Abnormal Occurrence Criteria and (2) the ACMUI Subcommittee’s report on a draft guidance document	07/24/2019 - 07/24/2019
To discuss issues related to the implementation of the medical regulations in Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material."	09/10/2019 - 09/11/2019

Number of Committee Meetings Listed: 5

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$90,709.86	$94,416.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$264,735.80	$207,740.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$20,667.38	$29,000.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$3,296.15	$6,300.00
18b(4). Travel and Per Diem to Non-member Consultants	$3,402.37	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$0.00
18d. Total	$382,811.56	$337,456.00
19. Federal Staff Support Years (FTE)	1.44	1.13

20a. How does the Committee accomplish its purpose?

The NRC staff believes that licensees, the general public, and medical professionals benefit when recognized experts provide advice to the staff. This advice enables staff to develop rules that will maintain public safety, while not inappropriately intruding upon the practice of medicine.The staff provides a summary of issues to be addressed during meetings, and the ACMUI discusses the issues and gives advice and makes recommendations to the Staff. Furthermore, the ACMUI keeps staff abreast of new developments. This ongoing communication helps ensure that staff is aware of important issues during critical stages of rule development. When issues that need special emphasis arise, working groups and subcommittees are formed.

20b. How does the Committee balance its membership?

Membership is balanced by placing individuals of diverse specialty on the committee. For instance, there are members who represent both diagnostic and therapeutic applications of medicine. There are members who have a regulatory function within their specialties. There is a member who represents medicine from an administrative standpoint, and there is a patient advocate member, who represents patients' interests. ACMUI members also

perform regular self-evaluations, in which they give feedback on the appropriateness of the committee's composition.

20c. How frequent and relevant are the Committee Meetings?

Committee meetings are generally held semi-annually. The committee will hold more frequent meetings when important issues emerge or when issues need timely resolution.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The NRC continues to strive to achieve its goal of creating risk-informed, performance-based regulations that provide for the health and safety of the public while imposing no unnecessary burden on licensees. Furthermore, the medical profession continues to see regular advances that create unique regulatory challenges. The advice and recommendations from medical professionals who are exposed to these advances is crucial to the NRC staff's ability to continue to regulate effectively.

20e. Why is it necessary to close and/or partially closed committee meetings?

Meetings are closed to conduct annual ethics briefings, annual allegations training, annual information security awareness training, conduct reviews of paperwork of a personal and confidential nature, and to discuss administrative matters that are purely internal to Committee business. It would be inappropriate to conduct these types of meetings openly. They must be conducted privately to allow Committee members the freedom to ask and answer personal questions and to protect individuals' privacy.

21. Remarks

None

Designated Federal Officer

Kellee Jamerson DFO

Committee Members	Start	End	Occupation	Member Designation
Bloom, Gary	09/23/2019	09/22/2023	Patients' Rights Advocate	Special Government Employee (SGE) Member
Dilsizian, Vasken	05/12/2014	05/11/2022	Nuclear Cardiologist	Special Government Employee (SGE) Member
Ennis, Ronald	03/18/2015	03/17/2023	Radiation Oncologist	Special Government Employee (SGE) Member
Green, Richard	05/27/2018	05/26/2022	Nuclear Pharmacist	Special Government Employee (SGE) Member
Martin, Melissa	08/19/2018	08/18/2022	Nuclear Medicine Physicist	Special Government Employee (SGE) Member
Metter, Darlene	03/05/2016	03/04/2020	Diagnostic Radiologist	Special Government Employee (SGE) Member
O'Hara, Michael	11/01/2014	09/30/2023	FDA Representative	Regular Government Employee (RGE) Member
Ouhib, Zoubir	04/15/2018	04/14/2022	Therapy Medical Physicist	Special Government Employee (SGE) Member
Palestro, Christopher	09/22/2011	09/21/2019	Nuclear Medicine Physician	Special Government Employee (SGE) Member
Schleipman, Arthur	09/16/2018	09/15/2022	Health Care Administrator	Special Government Employee (SGE) Member
Sheetz, Michael	09/29/2017	09/28/2021	Radiation Safety Officer	Special Government Employee (SGE) Member
Shober, Megan	04/15/2018	04/14/2022	Agreement State Representative	Special Government Employee (SGE) Member
Suh, John	10/18/2010	10/17/2018	Radiation Oncologist	Special Government Employee (SGE) Member
Weil, Laura	08/29/2011	08/28/2019	Patients' Rights Advocate	Special Government Employee (SGE) Member

Wolkov, Harvey 04/29/2019 04/28/2023 Radiation Oncologist Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

Narrative Description

The Committee provides input from the regulated medical community and the public that helps guide the NRC regulatory program.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	
Effective grant making	
Improved service delivery	✓
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

Cost savings from improved regulations save medical institutions and patients, but totals can not be calculated.

What is the approximate Number of recommendations produced by this committee

for the life of the committee?
326

Number of Recommendations Comments
Recommendations from 2007 to FY2019 are included in the current count.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
87%

% of Recommendations Fully Implemented Comments
Since 2007, 285 of 326 recommendations have been or will be fully implemented.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
16%

% of Recommendations Partially Implemented Comments
Since 2007, 54 of 326 recommendations have been or will be partially implemented or have pending status.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
NRC staff provides feedback at subsequent meetings by updating the Committee on the status of the list of recommendations.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☑
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☐

Action Comments

NA

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	
Publications	✓
Other	✓

Access Comments

http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html