	ITEM	DATE	STATUS	
1	The Committee endorsed that component of the current proposed rule re-defining medical events in permanent implant brachytherapy in terms of activity (i.e. source strength) rather than radiation dose).	1/6/2016	Accepted	Closed 3/7/18
2	The Committee endorsed, with reservation, designating the current proposed rule re-defining medical events in permanent implant brachytherapy as Compatibility Category C, with activity-based medical event metrics defined as an essential program element.	1/6/2016	Accepted	Closed 3/7/18
3	The Committee recommended changing the language for a "wrong-location" medical event in permanent implant brachytherapy from the current proposed language, "Sealed source(s) implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive," to **"Sealed source(s) implanted directly into a location discontiguous from the treatment site, as defined in the written directive."**	1/6/2016	Accepted	Closed 3/7/18
4	The Committee recommended revising the passage in lines 4182-4186 on page 167 in the Draft Final Rule as follows, thereby eliminating the dose-based criteria for a leaking source" medical event: **"3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; a leaking sealed source; or a sealed source or sources implanted into a location discontiguous from the treatment site, as defined in the written directive."**	1/6/2016	Not Accepted	Closed 3/7/18

	ITEM	DATE	STATUS	
5	The Committee endorsed the elimination of the preceptor-statement requirement for Board-certified individuals for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist.	1/6/2016	Accepted	Closed 3/7/18
6	With respect to the amended requirements for preceptor attestation for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the alternate pathway, the Committee endorsed changing the language for the preceptor attestation from the individual "…has achieved a level of competency to function independently…" for the authorization to **the individual can "…independently fulfill the radiation safety-related duties…" associated with the authorization being requested.**	1/6/2016	Accepted	Closed 3/7/18
7	The Sub-Committee recommended that the date of recognition by the NRC of a certifying board should not impact individuals seeking to be named as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the certification pathway. During the discussion, this recommendation was modified in the final report as follows: **The Sub-Committee recommends that NRC Staff consider providing guidance in the NUREG-1556, Volume 9 update to licensees on the ways individuals with board certifications prior to NRC's board recognition date may seek authorization.**	1/6/2016	Accepted	Closed 3/7/18

	ITEM	DATE	STATUS	
8	The Committee recommended that the NRC adopt the parent-breakthrough limits for radioisotope generators specified in the relevant Food and Drug Administration (FDA)-approved package inserts. During the discussion, the Committee recommended to eliminate this recommendation and instead, revise the general comments section of the report to suggest that NRC consider, in future rulemaking, establishing conformity with the FDA breakthrough-limit regulations.	1/6/2016	ACMUI Action	Closed 3/7/18
9	The Committee did not endorse the new requirement in the Draft Final Rule that licensees report to the NRC as well as to the manufacturer/vendor generator elutions with out-of-tolerance parent-breakthrough but, instead, recommends a single reporting requirement to the manufacturer/vendor.	1/6/2016	Not Accepted	Closed 3/7/18
10	The Committee endorsed allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license.	1/6/2016	Accepted	Closed 3/7/18
11	The Committee recommended that the designation of a board-certified authorized user, authorized medical physicist, or authorized nuclear pharmacist as the Radiation Safety Officer (RSO) or as an ARSO requires their board certification to include the designation, “RSO Eligible.”	1/6/2016	Not Accepted	Closed 3/7/18
12	The Committee did not endorse establishing a separate category of Authorized Users for parenteral administration of alpha-emitting radiopharmaceuticals but, instead, recommends deleting § 35.390(b)(1)(ii)(G)(4) in the current Draft Final Rule and revising the pertinent passage in § 35.390(b)(1)(ii)(G)(3) as follows, **“Parenteral administration of any radioactive drug for which a written directive is required.”**	1/6/2016	Partially Accepted	Closed 3/7/18

	ITEM	DATE	STATUS	
13	The Committee endorsed the elimination of the requirement to submit copies of NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or renewal.	1/6/2016	Accepted	Closed 3/7/18
14	The Sub-Committee recommended changing the "medical-events" language in lines 5531-5532 (page 232) of the Draft Final Rule from, "A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…," back to the language in the current Draft Final Rule, "A licensee shall report any event, except for an event that results from patient intervention…" During the discussion, the recommendation was modified in the final report as follows: **The Sub-Committee recommends changing the "medical-events" language in lines 5531-5532 (page 232) of the current version of the Draft Final Rule from, "A licensee shall report any event, except for an event that results from patient intervention…" back to the language published in the Proposed Rule as presented for public comment,** **"A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…,"**	1/6/2016	Not Accepted	Closed 3/7/18
15	The Committee endorsed the 2016 Rulemaking Subcommittee Report with modifications as listed above.	1/6/2016	NRC Action	Closed 3/7/18
16	Dr. Alderson formed a subcommittee to review and evaluate the training and experience requirements for all modalities in 10 CFR Part 35. Subcommittee members include: Dr. Langhorst, Dr. Metter, Dr. Palestro (chair), Dr. Suh and Ms. Weil. NRC staff resource: Maryann Abogunde.	2/25/2016	ACMUI Action	Open Indefinitely

	ITEM	DATE	STATUS	
17	The ACMUI recommended maintaining the current 700 training and experience hours under 10 CFR 35.390.	3/10/2016	NRC Action	Closed
18	The ACMUI recommended establishing a standing subcommittee to review the training and experience requirements for all modalities under 10 CFR Part 35.	3/10/2016	ACMUI Action	Closed
19	The ACMUI unanimously endorsed the training and experience for authorized users of alpha, beta, and gamma emitters under 10 CFR 35.390 subcommittee report.	3/10/2016	ACMUI Action	Closed
20	The NRC staff will provide data to the ACMUI for medical events reported over a five-year span for trending purposes.	3/17/2016	NRC Action	Closed
21	Dr. Alderson formed a subcommittee to 1) explore the impact of ME reporting and its impact on self-reporting (safety culture); 2) identify potential ways to improve effectiveness of self-reporting in support of a culture of safety; and 3) suggest ways to share ME reports and lessons-learned with the medical community to promote safety. Subcommittee members include: Mr. Costello, Dr. Dilsizian, Dr. Ennis, Dr. Langhorst (chair), and Ms. Weil. Mr. Ouhib will serve as a consultant to the subcommittee. NRC staff resource: Dr. Katie Tapp	3/18/2016	ACMUI Action	Closed
22	The NRC staff will provide the ACMUI with the draft final 35.1000 licensing guidance for the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon. Interested members will be encouraged to provide comments to the Working Group.	3/18/2016	NRC Action	Closed
23	Dr. Langhorst requested that NRC staff provide the ACMUI with the total number of medical use licensees within the United States (NRC and Agreement States).	3/18/2016	NRC Action	Closed

	ITEM	DATE	STATUS	
24	The ACMUI will contact their respective professional organizations to request and encourage interactions between the NRC and ACMUI with their organization.	3/18/2016	ACMUI Action	Open Indefinitely
25	The ACMUI have planned to hold the fall 2016 ACMUI meeting at NRC Headquarters on October 6-7, 2016. The back-up date is September 1-2, 2016.	3/18/2016	ACMUI Action	Closed
26	The Committee endorsed the elimination of the written directive with the understanding that there will be documentation in the medical record pre-procedure and post-procedure that would allow regulators to determine whether a medical event occurred.	6/24/2016	Accepted	Closed
27	The Committee endorsed the third pathway in which a radiologist could become an authorized user with the listed 80-hours of training and experience. However, the Committee did not support surgeons or others without a significant background in radiation (from a residency or other similarly intense education and practical experience) becoming Authorized Users for RSL with only 80 hours of training.	6/24/2016	Accepted	Closed

	ITEM	DATE	STATUS	
28	The Committee endorsed the modified definition of medical events (MEs) with the caveat that such an outcome would not be an ME if "the physician makes the determination not to explant the seed for various patient conditions (e.g. doing so would jeopardize the patient's wellbeing)." The Committee endorsed this change and supports exclusion from an ME under circumstances in which the physician deems removal would not be in the best interest of the patient. Additionally, the Committee endorsed the position that an ME has not occurred if the patient fails to return for the surgical removal procedure, considering this to be an instance of "patient intervention," provided the patient has been properly counseled about the importance of returning for the procedure and the risk of radiation exposure if the sources are not removed. Documentation of this counseling should be made in the patient's medical record.	6/24/2016	Accepted	Closed
29	The Committee recommended inclusion of the following in the Draft Guidance: "Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breastfeeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from the effected breast for this child." During the discussion, this recommendation was modified as follows: "Patient should be advised not to breast feed from a breast into which one or more radioactive seeds been implanted and not yet removed. Breast feeding is, of course, permissible once the seed(s) has(ve) been removed. In the event of seed rupture within the breast, the subcommittee recommends the patient be advised to never breast feed from either breast for this child."	6/24/2016	Not Accepted	Closed

	ITEM	DATE	STATUS	
30	The Committee endorsed the RSL Subcommittee report with the modifications above.	6/24/2016	ACMUI Action	Closed
31	The Committee recommended that the section entitled, “Licensing Guidance,” 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.”	8/10/2016	NRC Action	Closed
32	The Committee recommended to provide clarification of what is regulated under 10 CFR 35.200 and 10 CFR 35.1000. 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 Committee 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,	8/10/2016	NRC Action	Closed

	ITEM	DATE	STATUS	
	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.			
33	The Committee recommended to modify the language in the "Use of Ge-68/Ga-68 Generators" Section 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.	8/10/2016	NRC Action	Closed

	ITEM	DATE	STATUS	
34	The Committee agreed with the recommendation to modify the language in the "Authorized Individuals" Section to the following language: 4) Meets the criteria under 10 CFR 35.290, "Training for imaging and localization studies;" 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.	8/10/2016	NRC Action	Closed
35	The Committee agreed with the recommendation to modify the language in the "Training for individuals other than AUs and ANPs" Section 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.	8/10/2016	NRC Action	Closed

	ITEM	DATE	STATUS	
36	The Committee agreed with the recommendation to modify the language in the "Radiation Protection Program Changes" Section 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:	8/10/2016	NRC Action	Closed
37	The Committee endorsed the Ge-68/Ga-68 Subcommittee report.	8/10/2016	ACMUI Action	Closed
38	Dr. Alderson requested that the ACMUI discuss the nursing mothers guidelines during the Spring 2017 ACMUI Meeting.	10/6/16	ACMUI Action	Closed
39	The Committee recommended that staff issue a generic communication (information notice) regarding tubing issues (kinking, connection, hub etc.) during the administration of Y-90 microspheres brachytherapy.	10/6/16	NRC Action	Open
40	Dr. Pat Zanzonico stepped down from the subcommittee. Dr. Alderson appointed Mr. Frank Costello to the Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy Subcommittee. Subcommittee membership includes: Mr. Costello, Dr. Dilsizian, Dr. Ennis, Dr. Palestro, and Dr. Suh (Chair). Mr. Ouhib will be added to the subcommittee once he receives full voting rights. Dr. Katie Tapp is the NRC resource.	10/6/16	ACMUI Action	Closed

	ITEM	DATE	STATUS	
41	Dr. Alderson re-established the Patient Intervention Subcommittee. The subcommittee's new charge is to make a recommendation on what the definition of "patient intervention" should be. Subcommittee membership include: Mr. Costello, Dr. Dilsizian (Chair), Dr. Ennis, Dr. Suh, and Ms. Weil. Ms. Maryann Abogunde is the NRC resource.	10/6/16	ACMUI Action	Open
42	The Committee recommended that the Pathway 2 remain for the Y-90 Microsphere Brachytherapy Licensing Guidance. The NRC/OAS working group should determine what the requirements should be for the proctoring of cases by the manufacturer(s).	10/7/16	NRC Action	Open
43	The Committee recommended to support the update to the waste disposal section and the review of the Y-90 radiation safety issues in autopsy and cremation in the draft revision of the Y-90 Microsphere Brachytherapy Licensing Guidance.	10/7/16	NRC Action	Open
44	For the NorthStar Guidance Subcommittee: The Committee recommended that NorthStar provide a video clip of how the system operates in the training module.	10/7/16	NRC Action	Closed
45	For the NorthStar Guidance Subcommittee: Given the unique design and operation of the NorthStar system, the Committee agreed that NorthStar should have sole responsibility for the content of the training course and certification.	10/7/16	NRC Action	Closed
46	For the NorthStar Guidance Subcommittee: The Committee stated that it is important to clarify that a System Administrator can be any individual assigned by the AU without a specifically defined educational or training background. Given the unique role of the System Administrator, perhaps that individual should be named on the license.	10/7/16	NRC Action	Closed

	ITEM	DATE	STATUS	
47	For the NorthStar Guidance Subcommittee:The Committee recommended an explicit statement regarding the System Administrator Designee, although it may not have been intended, one could infer from the description of the system administrator designee that there can be only one designee. Presumably, there can, and should, be multiple System Administrator designees.	10/7/16	NRC Action	Closed
48	For the NorthStar Guidance Subcommittee:The Committee recommended that the appropriate time period allotted for training on the “changes” and the responsibility of the vendor/manufacturer to inform and train the applicants on changes in a timely manner be specified.	10/7/16	NRC Action	Closed
49	For the NorthStar Guidance Subcommittee: The Committee recommended that the guidance clarify whether the generator will be “non-operational” until ALL individuals handling the generator are trained in the changes, including the AU, RSO, system administrator, etc. or does it require only the AU to be trained on the “changes.” If the latter, once the AU is trained on the “changes”, is the AU then solely responsible for training all others on these changes? This should be stated.	10/7/16	NRC Action	Closed
50	For the NorthStar Guidance Subcommittee: The Committee recommended using the term, “individual tasks” throughout the document for consistency and to clarify that there is only one protocol and software program with this system.	10/7/16	NRC Action	Closed
51	For the NorthStar Guidance Subcommittee: The Committee recommended that the manufacturer’s procedures be reviewed and incorporated into the Licensing Guidance itself.	10/7/16	NRC Action	Closed
52	For the NorthStar Guidance Subcommittee: The Committee recommended that the term “higher than expected” be defined in terms of a maximum specific exposure or exposure-rate limit which a survey meter should be capable of measuring.	10/7/16	NRC Action	Closed
53	The Committee endorsed the NorthStar Mo-99/Tc-99m Generator (RadioGenix) Subcommittee Report.	10/7/16	ACMUI Action	Closed

	ITEM	DATE	STATUS	
54	The Committee tentatively scheduled the Spring 2017 Meeting for March 20-21, 2017. The back-up dates are April 25-28, subject to Commission availability.	10/7/16	ACMUI Action	Closed