

August 28, 2008

MEMORANDUM TO: Michael T. Lesar, Chief
Rulemaking, Directives and Editing Branch
Division of Administrative Services
Office of Administration

FROM: Edward M. Lohr
Rulemaking Branch B **/RA/**
Division of Intergovernmental Liaison
and Rulemaking, FSME

SUBJECT: REGULATORY HISTORY INDEX - PROPOSED RULE:
MEDICAL USE OF BYPRODUCT MATERIAL –
“AMENDMENTS/MEDICAL EVENT DEFINITIONS” (73 FR 45635)
RIN 3150-AI26

Enclosed is the regulatory history index of those documents of central relevance to the subject proposed rule. The ADAMS number is provided for each document or package. The proposed amendments would change the criteria for defining a medical event (ME) for permanent implant brachytherapy from dose-based to activity-based; add a requirement to report, as an ME, any administration requiring a written directive (WD) if a WD was not prepared; clarify requirements for WDs for permanent implant brachytherapy; and make certain administrative and clarification changes. The proposed rule titled “Amendments/Medical Event Definitions” was published in the *Federal Register* on August 6, 2008 (73 FR 45635).

Enclosure: Regulatory History Index

CONTACT: Edward M. Lohr, FSME/DILR
(301) 415-0253

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Regulatory History Index

SUBJECT: PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – AMENDMENTS/MEDICAL EVENT DEFINITIONS (73 FR 45635) RIN 3150-AI26

Accession Number	Title/Description	Document Date	Author	Public Availability
ML080350090	Part 35 Preliminary Draft Language for Proposed Changes Related to Medical Events in Brachytherapy.	2/7/2008	Lohr E M	Publicly Available
ML080390224	Availability of Preliminary Draft Rule Language For Medical Use of Byproduct Material - Amendments/Medical Event Definitions (RIN 3150-AI26).			Publicly Available
ML080520359	Part 35 Preliminary Draft Language dated February 21, 2008.	2/21/2008	Lohr E M	Publicly Available
ML080570266	2008/02/22-Comment (1) of Wayne Butler on PR 35 "Medical Use of Byproduct Material/Medical Event Definitions".	2/22/2008	Butler W	Publicly Available

Accession Number	Title/Description	Document Date	Author	Public Availability
ML080570270	2008/02/25-Comment (2) of Ray Van Ausdal on PR 35, "Medical Use of Byproduct Material-Amendments/Medical Event Definitions."	2/25/2008	VanAusdal R	Publicly Available
ML080590269	2008/02/26-Comment (3) of Haijun Song and Walter Furr Opposing Proposed Rule PR-35 regarding Medical Use of Byproduct Material - Amendments/Medical Event Defintions	2/27/2008		Publicly Available
ML080590276	2008/02/26-Comment (4) of American Association of Physicists in Medicine re Proposed Rule PR-35, Medical Use of Byproduct Material - Amendments/Medical Event Definitions.	2/26/2008		Publicly Available
ML080590277	2008/02/26-Comment (5) of Laura I. Thevenot on Behalf of The American Society for Therapeutic Radiology and Oncology, ASTRO, regarding PR 35 "Medical Use of Byproduct Material-Amendments/Medical Event Definitions".	2/26/2008	Thevenot L I	Publicly Available
ML080590278	2008/02/26-Comment (6) of Edwin M. Leidholdt, on Behalf of US Dept. of Veterans Affairs, Veterans Health Administration National Health Physics Opposing Proposed Rule PR-35 regarding Medical use of Byproduct Material - Amendments/Medical Event Definition	2/26/2008	Leidholdt E M	Publicly Available

Accession Number	Title/Description	Document Date	Author	Public Availability
ML080640929	2008/03/03-Comment (7) of Alexander J.B. McEwan on Behalf of The Society of Nuclear Medicine regarding PR 35, Medical Use of Byproduct Material - Amendments/Medical Event Definitions.	3/3/2008	McEwan A J	Publicly Available
ML080640971	2008/02/27-Email from Ralph Lieto on PR 35 regarding Medical Use of Byproduct Material - Amendments/Medical Event Definitions" stating that his comments will be late.	2/28/2008	Flannery C M	Publicly Available
ML080640977	2008/02/26-Comment (8) of Ralph P. Lieto on PR 35 regarding Medical Use of Byproduct Material-Amendments/Medical Event Definitions.	2/26/2008	Lieto R P	Publicly Available
ML080660095	2008/02/28-Comment (9) of Douglas E. Pfeiffer on Behalf of American Association of Physicists in Medicine (AAPM) on PR 35, Medical Use of Byproduct Material - Amendments/Medical Event Definition.	2/28/2008	Pfeiffer D E	Publicly Available
ML080780561	2008/03/05-Comment (10) of Conrad Nagle, Janice Campbell, and Cheryl Culver Schultz on Behalf of William Beaumont Hospital on PR 35 Regarding Medical Use of Byproduct Material Amendments/Medical Event Definitions.	3/5/2008	Campbell J Nagle C Schultz C C	Publicly Available

Accession Number	Title/Description	Document Date	Author	Public Availability
ML080840147	03/13/2008 - Letter from Emile L. Julian to Lynne Fairbent, American Association of Physicists in Medicine (AAPM), Responding to Letter Requesting for Extension of Comment Period re: PR 35, Medical Use of Byproduct Material.	3/13/2008	Julian E L	Publicly Available
ML081060362	Review and Concurrence: Medical Use of Byproduct Material- Amendments /Medical Definitions (Part 35)			Publicly Available
ML081370458	SECY-08-0080 - Proposed Rule: Medical Use of Byproduct Material - Amendments/Medical Event Definitions (RIN 3150-AI26)			Publicly Available
ML081910600	Implementation of Date, SRM-SECY-08-0080: Proposed Rule: Revisions to Part 35, Medical Use of Byproduct Material - Amendments /Medical Event Definitions (RIN 3150-AI26).			Publicly Available
ML082460541	Regulatory History for Proposed Rule: Medical Use of Byproduct Material – “Amendments/Medical Event Definitions” (73 FR 45635) RIN 3150-AI26			Publicly Available