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NUCLEAR REGULATORY COMMISSION  
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The enclosed documents comprise the regulatory history of the proposed rulemaking SECY 84 485 Medical Use of Byproduct 50 FR 30616.

Please put the documents in the document control system.

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Norman L. McElroy  
Material Licensing Branch  
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REGULATORY HISTORY OF THE REVISION OF 10 CFR Part 35 PUBLISHED FOR COMMENT  
ON JULY 26, 1985 (50 FR 30616)

DRAFTS AND TRANSCRIPTS

- D.1 draft regulation dtd 11-12-81
- D.2 draft regulation dtd 12-03-81
- D.3 draft regulation dtd 01-12-82
- D.4 SECY-83-62 dtd 02-10-83
- D.5 transcript of Commission mtg on SECY-83-62 held 04-19-83
- D.6 draft regulation dtd 08-18-83
- D.7 draft regulation dtd 12-07-83
- D.8 draft SECY dtd 02-13-84
- D.9 briefing handouts for regional staff mtgs, draft for Commission mtg,  
and actually used at the Commission mtg
- D.10 draft SECY dtd 07-13-84 for concurrence
- D.11 draft SECY dtd 10-15-84
- D.12 draft SECY insert dtd 12-27-84
- D.13 SECY-84-485 dtd 12-31-84
- D.14 transcript of Commission mtg on SECY-84-485 held 03-20-85
- D.15 50 FR 30616 dtd 07-26-85

HISTORICAL DOCUMENTS

- H.1 Part 35 FRN's dtd 01-11-56 through 04-22-85
- H.2 FRN 40 FR 31298 dtd July 25, 1975, "Radioactive drugs and radioactive  
biological products," by Food and Drug Administration
- H.3 notice To All Medical Licensees/BSinger dtd Summer 1976 re training  
and experience criteria
- H.4 notice To All Medical Licensees/WJDircks dtd June 16, 1980 re ALARA
- H.5 FRN 47 FR 54376 re training and experience criteria dtd 12-02-82
- H.6 AEC Licensing Guide/Medical Programs dtd 1965
- H.7 AEC Licensing Guide/Medical Programs dtd 1972
- H.8 Regulatory Guide 10.8 dtd January 1979 for comment
- H.9 Regulatory Guide 10.8 dtd October 1980
- H.10 Draft NUREG-0338, A Guide For Preparation Of Applications for Medical  
Programs dtd 11-01-77

## COMMENTS

- C.1 Comment ltrs dtd 02-08-82 through 06-17-83
- C.2 Memo WJWalker/JDeIMedico and PCVacca dtd 03-08-83 re communication of personal opinions with the Commissioners, w/encls
- C.3 Memo C.Roberts/JEZerbe dtd 06-13-83 providing OPE analysis of SECY-83-62
- C.4 Comments and comment analysis re 12-07-83 and 02-13-84 drafts
- C.5 Memo Commissioners/JEZerbe dtd 03-11-85 providing OPE analysis of SECY-84-485

## MANAGEMENT OF THE PROJECT

- M.1 memo JGDavis/RECunningham dtd 08-03-81 re project scope and status
- M.2 memo Regional Administrators/JGDavis dtd 03-08-82 requesting participation in task force and explaining project
- M.3 memo Those on Attached List/RECunningham dtd 05-05-82 requesting concurrence on proposed revision of 10 CFR Part 35 by 06-09-82
- M.4 memo JGDavis/WJWalker dtd 05-20-82 re schedule
- M.5 concurrences, non-concurrences, and comments on SECY-83-62 from ELD, RIII, RII, IC, SP, RI, RIV, RM, RES, RV, and ADM dtd June through Sept 1982
- M.6 memo WJDircks/JGDavis and R3Minogue dtd 01-12-83 transmitting SECY-83-62
- M.7 memo WJDircks/SJChilk dtd 04-19-83 requesting further information for Commissioners
- M.8 memo JEZerbe/Commissioner Roberts dtd 05-05-83 requesting OPE analysis of SECY-83-62
- M.9 notation vote sheets on SECY-83-62 from Commissioners Asselstine, Ahearne, and Roberts, and staff response to questions that were raised
- M.10 memo WJDircks/SJChilk dtd 06-23-83 directing revision of SECY-83-62 with all Commissioners concurring
- M.11 memo RECunningham/WJWalker dtd 08-17-83 re Part 35 schedule and staffing
- M.12 memo WJWalker/BSinger dtd 08-24-83 re applications with "plans" v applications with "procedures"
- M.13 memo Those on Attached List/RECunningham dtd 08-26-83 proposing new plan for revision of Part 35, and requesting appointment of cognizant individuals; responses attached
- M.14 memo VLmiller/WJWalker dtd 08-30-83 re staff support for revision
- M.15 memo DBMausshardt/RECunningham dtd 09-21-83 re scheduling of rewrite
- M.16 memo JGDavis/RECunningham dtd 11-21-83 with proposed task milestones, and JGDavis response requesting monthly progress reports
- M.17 memo Those on Attached List/RECunningham dtd 12-06-83 providing task force with proposed milestones and draft plan

- M.18 memo Those on Attached List/RECunningham dtd 12-06-83 providing task force with proposed milestones and draft plan
- M.19 memos JGDavis/RECunningham dtd 01-06-84 through 08-15-84 providing monthly progress reports on revision
- M.20 memo Those on Attached List/RECunningham dtd 02-13-84 requesting comment on draft SECY paper and regulatory guide
- M.21 memo JCMalaro/KRGoller dtd 06-22-84 re RES independent review of project
- M.22 memo Those on Attached List/RECunningham dtd 07-13-84 requesting concurrence on proposed revision of Part 35, and concurrences dtd 07-27-84 through 12-14-84
- M.23 memo WJDircks/RBMinogue dtd 08-30-84 transmitting RIR3 recommendation to continue with rulemaking, with review package as an enclosure
- M.24 memo JGDavis/RECunningham dtd 10-15-84 re SP and RIII non-concurrence
- M.25 note RECunningham/JGDavis dtd 11-30-84 with comments
- M.26 memo JGDavis/RECunningham c12-17-84 transmitting CP, memo WJDircks/JGDavis dtd 12-21-84 transmitting CP, and NRC Form 6 listing recommended distribution of CP
- M.27 memo WJDircks/JCHoyle dtd 03-29-85 requesting additional information re SECY-84-485, and staff responses memo SJChilk/WJDircks dtd 04-03-85, and JCHoyle/WJDircks dtd 04-15-85
- M.28 Office of Management and Budget approval of informaiton collection requirements
- M.29 Commissioners' notation vote response sheets on SECY-84-485
- M.30 memo WJDircks/SJChilk dtd 06-14-85 directing publication of FRN after making certain changes
- M.31 memo JMFelton/RECunningham dtd 07-10-85 requesting publication and distribution to licensees
- M.32 ltr MKUdall/JGDavis dtd 07-16-85 transmitting public affairs notice and FRN

#### BACKGROUND INFORMATION

- B.1 source document list for SECY-83-62 dtd 03-.5-83
- B.2 staff time per licensing action for 1980 and 1981, estimated number of licensees, and 1983 load
- B.3 analysis of compliance cost dtd 11-26-82
- B.4 note BWalker/NLMcElroy dtd 03-10-83 re dose calibrator checks and tests
- B.5 note JLieberman/JKlucsik dtd 09-16-82 re licensing technologists
- B.6 memo DBozik and NLMcElroy/JFKlucsik dtd 07-13-82 re release of patients

- B.7 various data re regulatory analysis
- B.8 United States Pharmacopoeia XX p 764 Sodium Pertechnetate Tc 99m Injection
- B.9 memo WJWalker and JDelMedico/JFKLucsik dtd 04-29-83 re licensing institutions and physicians
- B.10 memo multiple addressees/BSMallett dtd 12-11-81 re transfer of materials between hospitals
- B.11 memo multiple addressees/BSMallett dtd 12-11-81 re mobile vans
- B.12 notice to all medical licensees dtd 06-25-80 and 06-04-81 re radioactive waste
- B.13 medical applications check list dtd 01-07-82
- B.14 standard license conditions dtd 9-79 and 10-20-83
- B.15 petition dtd 11-05-81 from American Association of Physicists in Medicine re frequency of calibrating teletherapy dosimetry equipment
- B.17 memo BWalker/SLBaggett dtd 08-24-83 re teletherapy head survey
- B.18 IE Information Notice dtd 09-15-80 re teletherapy timer accuracy
- B.19 ltr PAParisi/NLMcElroy dtd 07-23-84 requesting permission to incorporate by reference new teletherapy calibration protocol
- B.20 note RECunningham/NLMcElroy dtd 01-18-85 re briefing for Commissioners' staff
- B.21 Draft NUREG-0338, A Guide For Preparation of Applications for Medical Programs, November 1, 1977
- B.22 FRN 44 FR 8242 dtd 02-09-79 Regulation of the Medical Uses of Radioisotopes; Statement of General Policy, and FRN 43 FR 11208 dtd 03-17-78 Regulation of the Medical Uses of Radioisotopes; Proposed Policy Statement