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Walker

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAY 20 1982

MEMORANDUM FOR: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

THRU: Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety

FROM: William J. Walker, Jr., Section Leader
Material Licensing Branch
Division of Fuel Cycle and Material Safety

SUBJECT: TASK NO. (PSB): 810892

Enclosed is Revision No. 2 to the subject Task Work sheet. This revision adjusts the date for sending the proposed rule to your office. The original estimate called for forwarding the package to the Commission in June, a highly speculative target date when the task force was first constituted in October 1981. A significant expansion in scope of the task force's original assignments (e.g., integration of MIS concepts and development of two companion regulatory guides), new regulatory requirements, (e.g, regulatory flexibility) and the recent inclusion of Regional representatives on the task force have caused delays in completing initial phases of the task force's work.

By copy of this memorandum Revision No. 2 to the Task Work sheet is provided to other interested parties.

William J. Walker, Jr., Section Leader
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. Task Work form
2. Schedule Revision #1
3. Schedule Revision #2

MEDICAL GENERAL LICENSE
MEDICAL AND ACADEMIC SECTION

TASK WORK

also 132134

Division of Fuel Cycle and Material Safety

PPSAS No.: 1322E

Task No. (PSB):810892

Date of Task: 8/15/81

Assigned Responsibility: W.J. Walker, Section Leader (Medical and Academic Licensing)

Level of Effort: Staff Weeks NMSS-15 RESS-10

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(74052) Task Force
E. Podolak (RESS)
D. Bozik (RESS)
R. O'Connel (NMSS)

Originated By: There is a need to streamline the process of licensing those materials' users who's radiation safety programs are generically similar. The medical nuclear medicine license is of this type.

Description: Qualified medical licensees would be authorized nuclear medicine groups I, II and III (10 CFR 35.100) under a general license. This represents a much broader use of a general license than in the past.

Product(s): (1) Staff paper to Commission for policy considerations.
(2) New, streamlined, license procedure.

Other Organization Inputs Required: RES, Sandia Corporation (Contractor)

Concurrences Required: SP, ELD, IE, RES, OPE

Schedule with Major Milestones:

Beginning Date: ASAP

First Draft: See attached Time / Schedule Estimates

Second Draft:

Final Draft:

Final:

Resource Implications: Resources to support this effort are not included in the current budget. They are being reprogramed by NMSS and RESS because it is felt that commutting resources at this time will make materials licensing more efficient in the future. Involvement of the medical licensing section leader will cause some minor slippages in medical licensing.

Division Director Signature

Time / Schedule Estimates for Medical General Licensing

Completion 1981-82	
October 30	Conduct regulatory analysis: 1. Value-impact statement 2. Small Business impact analysis 3. Paperwork reduction analysis 4. Write proposed changes to 10 CFR 35 IAW Periodic and systematic review fo regulations
January 30	Write proposed rule and commission paper Write Safety Analysis-comparing level of safety from general licensing to specific licensing 1. Get detail from I and E on types and frequences of non compliance 2. Frequency of items in deficiency letters
April 30	Obtain: 1. Agreement states comments 2. Paperwork reduction clearance 3. Rewrites as necessary 4. Medical Advisory Committee Review 5. Meeting with Executive Committee-SNM
June 4	Commission action-for publication in Federal Register
3 Months	Comment period and OMB clearance
3 Months	Analysis of comments and rewrites
1 Month	Concurrances (no agreement states)
1 Month	Commission Action

Revision No. 1

SCHEDULE ESTIMATES FOR MEDICAL LICENSING TASK FORCE

Due to a reordering of priorities within the time frame previously submitted, the following revised schedule will be followed.

October 30	Regulatory Analysis Input	
	1. Preliminary Value/Impact	completed
	2. Small business impact certification	completed
	3. Paperwork Reduction Analysis	ongoing
	4. Draft of proposed changes to 10 CFR 35 in accordance with periodic and systematic review of regulations	under revision
January 30	Proposed rule and Commission paper	3rd staff draft
	Review of items of licensee non-compliance from IE	completed
	Review of licensee deficiency letters	completed
	Meeting with Executive Committee of Society of Nuclear Medicine	completed January 26
March 19	Proposed rule and Commission paper to major NRC offices for office concurrence	
	Copies to ACMUI and Agreement States	
April 23	Comments on proposed rule and Commission paper due to Task Force from: 1. NRC Offices 2. Agreement States	
May 21	Completion of resolution of comments and rewrites as necessary	
June 4	Proposed rule to Commission for publication in the Federal Register	
	Paperwork Reduction Clearance prepared to go forward after Commission approval	
3 months	Comment period and OMB clearance	
3 months	Analysis of comments and rewrites	
1 month	Concurrences (no Agreement States)	
1 month	Commission action	

01/26/82

SCHEDULE ESTIMATES FOR MEDICAL LICENSING TASK FORCE

Due to a reordering of priorities within the time frame previously submitted, the following revised schedule will be followed.

October 30	Regulatory Analysis Input	
	1. Final Value/Impact	completed
	2. Small business impact certification	completed
	3. Paperwork Reduction Analysis	completed
	4. Draft of proposed changes to 10 CFR 35 in accordance with periodic and systematic review of regulations	completed
January 30	Proposed Rule and Commission paper	completed
	Review of items of licensee non-compliance from IE	completed
	Review of licensee deficiency letters	completed
	Meeting with Executive Committee of Society of Nuclear Medicine	completed
May 7	Proposed rule and Commission paper to major NRC offices for office concurrence	completed
	Copies to ACMUI and Agreement States	completed
June 9	Comments on proposed rule and Commission paper due to Task Force from: 1. NRC Office 2. Agreement States	
June 23	Completion of resolution of comments and rewrites as necessary	
June 30	Proposed rule to the Director of NMSS	
July	Proposed rule to the EDO	
August	Proposed rule to the Commission	
	Paperwork Reduction Clearance prepared to go forward after Commission approval	
3 months	Comment period and OMB clearance	
2 months	Analysis of comments and rewrites	
1 month	Concurrences (no Agreement States)	
1 month	Commission action	

SCHEDULE ESTIMATES FOR MEDICAL LICENSING TASK FORCE

October 30	Regulatory Analysis Input	
	1. Final Value/Impact	completed
	2. Small business impact certification	completed
	3. Paperwork reduction analysis	completed
	4. Draft of proposed changes to 10 CFR 35 in accordance with periodic and systematic review of regulations	completed
January 30	Proposed rule and Commission paper	completed
	Review of items of licensee non-compliance from IE	completed
	Review of licensee deficiency letters	completed
	Meeting with Executive Committee of Society of Nuclear Medicine	completed
May 7	Proposed rule and Commission paper to major NRC offices for office concurrence	completed
	Copies to ACMUI and Agreement States	completed
June 9	Comments on proposed rule and Commission paper to be received from Agreement States	completed
*August 30	Comments on proposed rule and Commission paper to be received from NRC Offices	
*September 17	Completion of resolution of comments and rewrites as necessary	
	Proposed rule to the Director of NMSS	
*September 30	Proposed rule to the EDO	
*October 31	Proposed rule to the Commission	
	Paperwork Reduction Clearance prepared to go forward after Commission approval	
3 months	Comment period and OMB clearance	
2 months	Analysis of comments and rewrites	
1 month	Concurrences (no Agreement States)	
1 month	Commission action	

*Revision No. 3 date

8/26/82

NMSS TASK SUMMARY SHEET 7/19/82

Revised Task Work

Purpose of Submission: ___ New Task _X_ Revised Task Date: August 26, 1982

Task Title: Proposed Revision of 10 CFR Part 35 on Human Uses of Byproduct Material

Task #: (PSB): 810892

PPSAS #132134

Task Description:

Modify regulation of the medical use of byproduct material. The task will involve two-steps: (1) revise the regulations, 10 CFR Part 35, to provide a single source of the requirements specifically related to human use of byproduct materials, and (2) revise the medical license review process. The latter step would allow use of an automated management information system (MIS).

Project Manager:
(Name/Office Symbol/Phone) William J. Walker, Jr., FCML, 74052

Product(s): 1) Staff paper to Commission for policy considerations.
2) New, streamlines, license procedure.

Other Organization Inputs Required: RES

Concurrences Required: SP, ELD, IE, ADM, Regional Administrators

Schedule:

Milestone	Date

See Attached Time / Schedule Estimates

Resource Implications: (Provide for duration of Task by FY)

Required Resources: FY8_: _____SY, _____$K; FY8_: _____SY, _____$K; FY8_: _____SY, _____$K
Budgeted Resources: FY8_: _____SY, _____$K; FY8_: _____SY, _____$K; FY8_: _____SY, _____$K

Source(s) of Unbudgeted Funds (If Necessary): Resources to support this effort are not included in the current budget. They are being reprogramed by NMSS and RES because it is Felt that the committing resources at this time will make materials licensing more efficient in the future. Involvement of the Medical Licensing Section Leader will cause some minor slippages in medical licensing.

Impact(s) of Reprogramming (If Necessary):

Approval:

Division Director
Date:

NMSS Director
Date:

Enclosure 1

PART: 35

OTHER AFFECTED PART(S): None Draft Regulatory Agenda c 8 82

FEDERAL REGISTER CITATION: Not yet published

SUBJECT: Medical Licenses for Human Use of Byproduct Material

SUMMARY: Description. The proposed rule would completely revise Part 35. This part contains the requirements and procedures applicable to a physician or medical institution that seeks to obtain a license authorizing the human use of byproduct material. The proposed rule would simplify the medical licensing process by adopting a "performance standard" approach to medical licensing. The proposed rule would set out all the requirements a licensee must meet yet allow the licensee flexibility in meeting the requirements. The proposed rule would be consistent with regulatory reform objectives while maintaining the current level of protection to the health and safety of the medical worker and the general public.

Objective. To simplify the medical licensing process and reduce the administrative burden on the licensee and the NRC by (1) including all the requirements a medical licensee must meet in the regulations; (2) eliminating or modifying administrative requirements not essential to safety; (3) simplifying the application form which, together with an automated licensing system, will create a more efficient licensing process; and (4) reducing the paperwork burden for the licensee and the NRC.

Background. The medical use of byproduct material has increased substantially over the past 30 years in terms of the number and types of procedures performed. To keep pace with radiation safety in a rapidly changing field, many requirements were imposed as license conditions or implied in regulatory guides. In addition, current practices require that each new and renewal application be complete without reference to any previous submittal. Over the past few years, the practice of nuclear medicine has become more sophisticated and radiation safety methodology and procedures have become more uniform. This permits NRC to propose simplifying the licensing process by codifying all requirements into a simple set of requirements contained in the proposed regulation and simplify the license application form to eliminate a detailed explanation of the procedures involved. An earlier rule on which the NRC was considering action that would clarify the responsibilities of various echelons of nuclear medicine personnel has been incorporated into this proposed revision of Part 35.

Legal Basis. 42 U.S.C. 2111, 2201, 2232, 2233.

TIMETABLE: Commission action on the proposed rule is scheduled for ~~June 1982.~~ AUG '82.

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11/24/81

MEDICAL LICENSING TASK FORCE

(Revision to Part 35)

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