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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 19, 1993

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner Curtiss
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: AGENDA FOR IMPROVEMENTS TO THE MEDICAL USE PROGRAM

In the Commission's Staff Requirements Memorandum of March 31, 1993, the staff was directed to "...review its present tracking systems and compile an overall list of ongoing and planned medical action items and projects. The action items should be prioritized and categorized with an estimated date of completion." A copy of that list as well as a summary arranged chronologically is provided for the Commission's information with this memorandum.

The staff had begun efforts to develop a data base in this regard prior to receipt of the SRM. In assembling this data base, the staff examined a variety of documents which contained recommendations, commitments or direction to make programmatic improvements in the medical area. These included Commission papers, Staff Requirements Memoranda, Minutes of ACMUI meetings, the IIT findings, and internal memoranda. Each such recommendation, commitment or direction was identified as a task and coded according to its source.

Each task was reviewed and categorized in terms of the type of product or action required, e.g. inspection guidance, licensing guidance, regulatory guidance, enforcement guidance, rulemaking, policy or other. Tasks were also assigned a tentative due date and priority. In addition, wherever possible, related tasks were combined and cross-referenced. The great majority of the tasks in the agenda are NMSS responsibilities. At present, the listing of tasks does not contain resource estimates. In accordance with Commission direction in the March 31 SRM, the staff will review its list to consider FTE and funding costs and will incorporate that information into the Medical Management Plan due on July 31, 1993.

Enclosure 1 is a summary of the tasks contained in the data base, and is arranged chronologically by due date of the task. Each item in Enclosure 1 also lists the track number of the more detailed task description provided in Enclosure 2. This allows for cross-referencing between the two lists.

It is important to note that this initial effort is only directed toward organizing and assigning priorities to the known tasks based on direction and program policy at the present time. Future efforts such as the Medical Management Plan, the internal management review, commitments made in the Glenn hearing of May 6, and, in the longer term, the external program review have the potential to significantly affect the priorities and due dates of the current tasks as well as add new tasks to the data base.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Chronological Summary
2. Comprehensive List

cc: OGC
SECY
OCA
OPA

ENCLOSURE 1

Organization Codes:
(Source, support)

C - Commission
E - EDO
N - NMSS
R - Regions
X - Research
D - AEOD
I - IIT
P - State Programs
S - Agreement States
A - ACMUI
M - Medical Community (ACNP, SNM, etc.)
G - OGC
O - Other

Category Codes:

IG - Inspection Guidance
LG - Licensing Guidance
RG - Regulatory Guidance (for licensees)
RM - Rulemaking
PO - Policy
O - Other Action (Analysis, Evaluation, etc.)

Medical Program Action Items

Printed: 05/13/93 14:09

Due Date: 04/06/93 Item: Track #27
Priority: H ACNP/SNM petition of 2/10/92 contends current fee schedule
Category: O adversely impacts medical licensees. (Completed 4/9/93)
Lead: Glenn

Actions: Prepare comments for LFMB.

****

Due Date: 04/15/93 Item: Track #43
Priority: H Staff may wish to review for each misadministration
Category: O classified as an AO, licensee's written reports to patients
Lead: Glenn versus those submitted to NRC.

Actions: Prepare memo based on meeting with OGC & OI to discuss
feasibility. (Completed by memo of 4/19/93; see Item #70)

****

Due Date: 04/15/93 Item: Track #44
Priority: H Review guidance & guides on Brachytherapy in light of IIT
Category: LG findings re: Indiana, PA incident.
Lead: Glenn

Actions: Issue bulletin to all HDR users (Completed 4/20/93);
consider longer term actions consistent with IIT memo.

****

Due Date: 04/30/93 *Item:* *Track #11*
Priority: H Abnormal Occurrence (AO) Reporting Criteria
Category: PO Review and revise AO reporting criteria.
Lead: Jordan

Actions: Prepare Commission Paper on revision of AO reporting criteria to specifically address misadministrations. (Comp.)

****

Due Date: 04/30/93 *Item:* *Track #70*
Priority: H Need for clarification of apparent weaknesses in 10CFR 35.33
Category: O regarding patient notification.
Lead: Glenn

Actions: Prepare memo to OGC requesting clarification of current rule language & whether additional rulemaking is needed. (Completed 4/19/93)

****

Due Date: 05/15/93 *Item:* *Track #09*
Priority: H Inspection/Enforcement guidance for QM Rule.
Category: IG Issue guidance for performance-based inspections of QM
Lead: Glenn programs.

Actions: Issue revised TI & field notes for QM program inspections. (Completed 4/5/93) Issue Enforcement Guidance Memorandum (Completed 4/30/93)

****

Due Date: 05/30/93 *Item:* *Track #35*
Priority: H Develop guidance document on licensee responsibilities in
Category: RG event of misadministration. Include reporting, patient
Lead: Glenn notification and investigation of event.

Actions: Develop Information Notice.

****

Due Date: 05/30/93 *Item:* *Track #41*
Priority: H Review existing policies/requirements/guidance on proper
Category: IG role of medical consultants in assisting NRC.
Lead: Combs

Actions: Revise MC 1360 to address issue and provide guidance to
regional and HQ staff.

****

Due Date: 05/30/93 *Item:* *Track #10*
Priority: H Licensing Guidance
Category: LG Complete SRP for Type A Broad Scope (updating P&GD).
Lead: Glenn Submit revision to RG 10.5 for Broad Scope to Research.

Actions: Complete SRP & submit revised Reg Guide for Broad Scope to
Research.

****

Due Date: 06/01/93 *Item:* *Track #20*
Priority: H Contractor to review QM plans for adequacy & develop
Category: O tracking system showing status of reviews.
Lead: Glenn

Actions: Award Contract.

****

Due Date: 06/01/93 *Item:* *Track #45*
Priority: H Revise licensing guidance in FC 86-4 which appears to be
Category: LG outdated & not well integrated with NRC regulations.
Lead: Glenn

Actions: Issue revised FC 86-4.

****

Due Date: 06/15/93 *Item:* *Track #32*
Priority: H Nominate senior NRC manager to perform mgt. review of exist-
Category: O ing medical program. Coordinate review with med. management
Lead: Paperiello plan & focus on whether program is being efficiently
implemented.

Actions: Perform management review of existing medical program.

****

Due Date: 06/15/93 *Item:* *Track #22*
Priority: H Upon Commission approval of SOW, prepare proposal package
Category: O for National Academy of Sciences' Review of Medical Program.
Lead: Rathbun

Actions: Prepare proposal package for NAS Review of Medical Program.

****

Due Date: 06/30/93 *Item:* *Track #46*
Priority: H Revise insp. guidance to address HDR Brachytherapy & cover
Category: IG multiple places of use, situations where RSO can't promptly
Lead: Combs respond & license amendments greatly expanding licensee's
operations scope.

Actions: Issue TI for inspection of HDR afterloaders.

****

Due Date: 06/30/93 *Item:* *Track #53*
Priority: H Evaluate NRC's process for: a) assessing exposure & conse-
Category: IG quences, & b) notifying individuals & authorities following
Lead: Combs following elevated exposure to the public. Issue guidance as appropriate.

Actions: Incorporate IIT lessons and issue Manual Chapter.

****

Due Date: 06/30/93 *Item:* *Track #42*
Priority: M Review existing policies/requirements on retention of
Category: O records including what records must be retained and for how
Lead: Combs long.

Actions: Meet with OGC and request legal analysis of basis for longer retention.

****

Due Date: 06/30/93 *Item:* *Track #52*
Priority: A Evaluate performance & design of PrimAlert-10 ARMs.
Category: O Take followup action as required to resolve issue of
Lead: Combs spurious alarms & need for confidence by users.

Actions: Write to manufacturer for evaluation of nonionizing RF's or EMF's re: Spurious alarms. Issue TI to Regions to include in routine inspection program.

****

Due Date: 07/15/93 Item: Track #28
Priority: H Consider issue of expanded NRC followup of patients subject
Category: PO to misadministrations; also refer to external group for
Lead: Glenn consideration.

Actions: Refer to external group for consideration.

****

Due Date: 07/30/93 Item: Track #25
Priority: H Provide training to Regions on QM rule.
Category: IG
Lead: Glenn

Actions: Followup training for Regions on interim final field notes
& temporary instruction.

****

Due Date: 07/30/93 Item: Track #01
Priority: H Develop med. mgt. plan to include long term objectives,
Category: PO umbrella policy, strategy for achieving those objectives, &
Lead: Glenn provision for annual update. Coordinate with ACMUI and
Agreement States.

Actions: Prepare management plan.
Incorporate Commission direction regarding evolution of
program and consistency with policy statement.

****

Due Date: 07/30/93 *Item:* *Track #30*
Priority: H Reassess base civil penalties regarding deterrence.
Category: O
Lead: Lieberman

Actions: Evaluate need to increase base civil penalties.

****

Due Date: 07/30/93 *Item:* *Track #31*
Priority: M Analysis on whether the evolution of the NRCs medical use
Category: O program has been consistent with the 1979 statement of Comm.
Lead: Glenn policy & whether any changes to the policy are warranted.

Actions: Incorporate into medical management plan; also refer to external group. Work into all rulemakings a statement of consistency.

****

Due Date: 08/01/93 *Item:* *Track #04*
Priority: H Conduct misadministration events analysis & summarize root
Category: O causes & corrective actions.
Lead: Rathbun

Actions: Publish NUREG summarizing results.

****

Due Date: 08/23/93 *Item:* *Track #63*
Priority: H Continue to allow physician-directed departures from package
Category: RM inserts: extension of time period under interim final rule.
Lead: Bahadur

Actions: Issue final rule, revising Part 35.

****

Due Date: 09/30/93 *Item:* *Track #03*
Priority: H QA Plan for HDR Afterloaders.
Category: O Contract to examine requirements, QA procedures, devise
Lead: Glenn critical components & risk of high dose rate devices &
provide model QA/QC program.

Actions: Develop QA/QC plan for HDR Afterloaders.

****

Due Date: 09/30/93 *Item:* *Track #05*
Priority: H Human Factors studies
Category: O Teletherapy, Brachytherapy, high dose rate
Lead: Kauffman Conduct human factors study. Determine utility of risk
analysis techniques.

Actions: Issue NUREG CR summarizing results of HF studies.

****

Due Date: 09/30/93 *Item:* *Track #58*
Priority: H Revise inspection guidance to include a provision to trigger
Category: LG consideration for licensees whose programs have
Lead: Combs significantly changed.

Actions: Develop criteria and prepare P&G Directive.

****

Due Date: 09/30/93 *Item:* *Track #14*
Priority: M NRC should fund a national study of the impact of regulation
Category: O on all uses of byproduct material in medicine. Study should
Lead: Combs be conducted by a University of neutral professional group.

Actions: Evaluate for inclusion in Regulatory Impact Survey.

****

Due Date: 09/30/93 *Item:* *Track #02*
Priority: M Develop a methodology for assessing risk significance of use
Category: O of medical devices & examine QA issues for gamma knife.
Lead: REC/GLENN

Actions: Develop NUREG on Methodology and QA issues.

****

Due Date: 09/30/93 *Item:* *Track #68*
Priority: M Prepare Policy & Guidance on Temporary exemptions for
Category: LG Emergency/Humanitarian Reasons.
Lead: Glenn

Actions: P&GD would provide Region with guidance on how to proceed in granting temporary exemptions from the regulations for emergency/humanitarian reasons, such as patient release outside of criteria in 35.75.

****

Due Date: 10/01/93 *Item:* *Track #37*
Priority: M Develop criteria for when a misadministration warrants an
Category: O AIT or IIT.
Lead: Jordan

Actions: Revise directive 8.3, NRC Incident Investigation Program to include criteria that may warrant AIT or IIT for misadministrations.

****

Due Date: 10/30/93 *Item:* *Track #60*
Priority: H Eval need for assisting nonradioactive waste processing
Category: O industry in establishing guidance for detecting & obtaining
Lead: Austin/Combs expert assistance for handling of radioactive materials.
Assist in developing guidance.

Actions: Develop pamphlet for non-radiation waste processors, incorporating IIT lessons.

****

Due Date: 10/30/93 *Item:* *Track #61*
Priority: H Evaluate Southwest Research's final report on source wire
Category: O failure and document findings.
Lead: Haughney

Actions: Evaluate and make recommendations.

****

Due Date: 11/30/93 *Item:* *Track #12*
Priority: H Part 35 Rulemaking on Admin of Byproduct Material to
Category: RM Pregnant and Breastfeeding Women.
Lead: Bahadur

Actions: Revise Part 35 to address need for licensees to determine pregnancy or nursing status of patients prior to administration.

****

Due Date: 12/30/93 *Item:* *Track #48*
Priority: H Revise licensing guidance for HDR Brachytherapy & review
Category: LG existing guidance for all other therapy to ensure it is
Lead: Glenn current.

Actions: Evaluate resource requirements/availability for all other guidance.

****

Due Date: 12/30/93 *Item:* *Track #54*
Priority: H Evaluate need to further define licensee responsibility for
Category: O assessing radiation exposure & notifying members of public &
Lead: Combs authorities. Issue guidance as appropriate.

Actions: Staff will evaluate need for rule change.

****

Due Date: 12/30/93 *Item:* *Track #59*
Priority: H For near term & where indicated, conduct inspections of
Category: IG licensees whose programs have significantly expanded or
Lead: Combs changed since last routine inspection.

Actions: Issue memo to Regions to poll licensing staff & perform inspections, as necessary. Complete inspections.

****

Due Date: 12/30/93 *Item:* *Track #19*
Priority: L NRC should expand address list for mailings to include not
Category: O only licensee mgt. but also RSO & Chief of Service for each
Lead: Combs authorized user, and use newsletters of professional societies for informing users.

Actions: Evaluate feasibility/cost of expanding LTS.

****

Due Date: 12/30/93 *Item:* *Track #15*
Priority: M NRC should explore substitution of voluntary accreditation
Category: O by professional organizations for some of the NRC inspection
Lead: Glenn processes.

Actions: OGC to prepare legal analysis of substitution.
Staff will evaluate feasibility of substitution of ACNP, ACR processes in Commission paper with recommendations.

****

Due Date: 12/30/93 *Item:* *Track #51*
Priority: M Evaluate need to further define RSO & authorized user
Category: O responsibilities. Issue new or revised guidance, as
Lead: Glenn appropriate.

Actions: Evaluate need for guidance for authorized users.

****

Due Date: 12/30/93 *Item:* *Track #69*
Priority: M Prepare Policy & Guidance directive for master materials
Category: LG licensing/inspection manuals (IMAB 731).
Lead: Glenn

Actions: Prepare P&G Directive.

****

Due Date: 12/30/93 *Item:* *Track #71*
Priority: M Develop inspection manual guidance regarding verification of
Category: IG newly-licensed activities & supervision under 35.25 guidance
Lead: Combs Coordinate with IMAB..

Actions: Update IP 87100 and Manual Chapter 2800.

****

Due Date: 12/31/93 *Item:* *Track #34*
Priority: H Formal guidance will be developed for routine and reactive
Category: IG inspections re: QM Rule.
Lead: Glenn

Actions: Finalize field notes & inspection procedure.

****

Due Date: 01/01/94 *Item:* *Track #62*
Priority: H Inconsistency between revised Part 20 Public Dose limits &
Category: RM Patient release criteria in 35.75 should be clarified
Lead: Cool (incorporate ACNP petition).

Actions: Issue final rule revising Part 35.

****

Due Date: 02/28/94 *Item:* *Track #64*
Priority: H Rev. Pt.35 to allow departures fr/pkg inserts create
Category: RM category of auth. nuc. pnarm., allow physician authorized
Lead: Bahadur users & auth. nuc. pharm to compound radioactive drugs,
allow research in human subjects...

Actions: Issue final rule revising Parts 35, 32 and 30.

****

Due Date: 03/01/94 *Item:* *Track #26*
Priority: H Revise Part 35 and Reg Guide 10.8 to address remote
Category: RM afterloader brachytherapy & gamma stereotactic surgery.
Lead: Glenn

Actions: Issue user need memo to RES to revise Part 35 & Reg. Guide 10.8. Complete QA plan for Gamma Knife (#2) remote afterloaders (#3). Complete Human Factors studies. (#5). Use input to develop user need memo.

****

Due Date: 03/01/94 *Item:* *Track #55*
Priority: H Eval. need to update & integrate existing requirements.
Category: LG Guidance & inspection procedures for HDR Afterloaders. Issue
Lead: Glenn new or revised requirements & guidance, as appropriate.

Actions: Incorporate results of guidance & research into user need memo to RES to revise Part 35.

****

Due Date: 03/01/94 *Item:* *Track #56*
Priority: H Eval. performance based approach vs schooling or
Category: O certifications to verify adequate rad. safety knowledge of
Lead: Glenn HDR afterloader users. Issue new or revised requirements or guidance, as appropriate.

Actions: Conduct evaluation, discuss with ACMUI and provide recommendations.

****

Due Date: 03/30/94 *Item:* *Track #66*
Priority: M Review medical field notes, specifically Nuclear Medicine
Category: IG field notes (diagnostic component) to determine savings of
Lead: Glenn/Combs time to divert to QM inspections. (IMAB 1149)

Actions: Revise QM field notes & inspection guidance.

****

Due Date: 06/01/94 *Item:* *Track #21*
Priority: H Contractor to review QM plans for adequacy & develop
Category: O tracking system showing status of reviews.
Lead: Glenn

Actions: Complete review and issue final report.

****

Due Date: 06/01/94 *Item:* *Track #57*
Priority: H Eval licsng interface & juris. betw NRC/FDA & states/agree-
Category: O ment states for sealed sources & devices including licensee
Lead: Glenn/Haugh. requirements for design reviews & QA/QC. Execute new or
revised agreements, as appropriate.

Actions: Coordinate with FDA/Agreement States.
Prepare evaluation of interface & jurisdiction issues.
Develop Commission paper.

****

Due Date: 06/30/94 *Item:* *Track #16*
Priority: M NRC should establish testing process for physicians & RSOs
Category: PO to evaluate competence.
Lead: Glenn

Actions: Evaluate feasibility of developing testing process.

****

Due Date: 06/30/94 *Item:* *Track #17*
Priority: M NRC should monitor adequacy of radiation safety component of
Category: O consultant rad. safety courses, residency programs, & board
Lead: Glenn certification courses.

Actions: Evaluate feasibility of monitoring adequacy of programs.

****

Due Date: 06/30/94 *Item:* *Track #33*
Priority: M Duties, functions, & responsibilities of an RSO for a
Category: RG licensed program need to be defined.
Lead: Glenn/Combs

Actions: Develop and publish NUREG for RSOs.

****

Due Date: 09/30/94 *Item:* *Track #06*
Priority: M Reassessment of training & experience criteria and precept-
Category: O oring process for physician authorized users by Visiting
Lead: Glenn Medical Fellow.

Actions: Evaluate need to revise training & experience criteria in
Part 35 & need to revise preceptoring process.

****

Due Date: 09/30/94 *Item:* *Track #65*
Priority: M Prepare P&GD on acceptable training and
Category: LG experience for physician-authorized users.
Lead: Glenn

Actions: Develop P&GD.

****

Track #07

Due Date: 12/30/94
Priority: L
Category: O
Lead: Glenn

Item:
Evaluate Part 35
Prescriptive vs. performance based regs. & deregulations
Regulations will be reviewed to determine if need to amend to allow greater flexibility.

Actions: Review Part 35 to determine if revision is needed to provide greater flexibility.

****

Track #08

Due Date: 12/30/94
Priority: L
Category: O
Lead: Glenn

Item:
Part 35
Evaluate need for training & experience requirements for supervised individuals.

Actions: Evaluate Part 35 requirements for supervision, training, & experience. Determine if revision is necessary.

****

Track #13

Due Date: 12/30/94
Priority: L
Category: RG
Lead: Glenn

Item:
NRC should prepare syllabus that can serve as basis for didactic basic radiation safety training of physicians for licensure.

Actions: Evaluate need for syllabus.

****

Track #67

Due Date: 04/30/95
Priority: M
Category: RG
Lead: Bahadur/Glen

Item:
Provide Commission with assessment of the effectiveness of QM Rule at annual briefing 3 years after rule becomes effect ive.

Actions: Gather data regarding implementation, monitor QM enforcement actions; evaluate need for comprehensive QM program.

****

Medical Program Action ems

Printed: 05/13/93 08:48

Due Date:
Priority:
Category: O
Lead: Glenn

Item: Track #18
NRC should revise 10 CFR 35.920 (Trng. for Imaging and Localization) & 10CFR 35.930 (Training for Therapeutic Use of Radiopharmaceuticals to more appropriately reflect knowledge base.

Actions: Incorporated into action for Item #6.

****

Due Date:
Priority:
Category: O
Lead: Glenn

Item: Track #23
ACNP expressed a desire to explore possibility of NRC recognition of its Practice Audit Program as alternative to inspection of the audit program.

Actions: Incorporated into action for Item #15.

****

Due Date:
Priority:
Category: O
Lead: Glenn

Item: Track #24
American College of Radiology (ACR) expressed interest in discussions w/ NRC re: acceptance of a voluntary QA program.

Actions: Incorporated into action for Item #15.

****

Due Date:
Priority:
Category: O
Lead: Combs

Item: Evaluate need for specific requirement, together with implementing guidance, imposing a duty on licensee to inform other persons exposed as a result of misadministration.

Track #36

Actions: Incorporate into action for IIT Item #54.

****

Due Date:
Priority:
Category: O
Lead: Jordan

Item: Develop criteria for misadministrations that are abnormal occurrences, identifying what efforts NRC will use to meet its statutory reporting obligations under Section 208.

Track #38

Actions: Incorporate into action for Item #11.

****

Due Date:
Priority:
Category: IG
Lead: Combs

Item: Develop criteria for following up with patients suffering acute present injury or possibility of radiation illness after misadministrations.

Track #39

Actions: Incorporate into revision to MC 1360 in Item #41.

****

Due Date:
Priority:
Category: IG
Lead: Glenn

Item: Review draft & final guidance on QM Program to ensure inspectors properly emphasize licensee's duty to report misadministrations to patients & referring physicians.

Track #40

Actions: Incorporated into guidance development addressed in Items #09 and #34.

****

Due Date:
Priority:
Category: O
Lead: Glenn

Item: Track #47
Consider revisions to Part 35 to eliminate list of sources in 35.400; clarify which provisions apply to HDRs & to LDRs; & need for additional provisions for either.

Actions: Incorporate into action for Item #26.

****

Due Date:
Priority:
Category: O
Lead: Haughney

Item: Track #29
Conduct analysis of adequacy of NRC, FDA & Agreement States review of medical devicer.

Actions: Incorporate into related IIT Item #57.

****

Due Date:
Priority:
Category: IG
Lead: Combs

Item: Track #49
Regional inspectors need an inspection procedure for the fo lowup of misadministration reports & other radiation th rapy events.

Actions: Incorporated into Items #9 and #34.

****

Due Date:
Priority:
Category: IG
Lead: Combs

Item: Track #50
Ensure availability of current inspection guidance for HDR Brachytherapy & all other therapy programs.

Actions: Incorporate into related IIT Item #55.

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Number of Records
71

ENCLOSURE 2

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 01

Source Code: N Document No.: 001 Doc. Date: 09/08/92

Document: Memo on Medical Management Plan

Description: Develop med. mgt. plan to include long term objectives, umbrella policy, strategy for achieving those objectives, & provision for annual update. Coordinate with ACMUI and Agreement States.

Action: Prepare management plan.
Incorporate Commission direction regarding evolution of program and consistency with policy statement.

Notes: Action incorporates Commission direction in SRM of 6/23/92 (Item #31).

PRIORITY: H

ACTION NO.:

Category 1: PO
Category 2: O
Category 3:

DUE DATE: 07/30/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 02

Source Code: N Document No.: 001 Doc. Date: 09/08/92

Document: Memo on Medical Management Plan

Description: Develop a methodology for assessing risk significance of use of medical devices & examine QA issues for gamma knife.

Action: Develop NUREG on Methodology and QA issues.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 09/30/93

Resources: 0.0

Lead: REC/GLENN

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 03

Source Code: N Document No.: 001 Doc. Date: 09/08/92

Document: Memo on Medical Management Plan

Description: QA Plan for HDR Afterloaders.
Contract to examine requirements, QA procedures, devise critical components & risk of high dose rate devices & provide model QA/QC program.

Action: Develop QA/QC plan for HDR Afterloaders.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 09/30/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 04

Source Code: N Document No.: 001 Doc. Date: 09/08/92

Document: Memo on Medical Management Plan

Description: Conduct misadministration events analysis & summarize root causes & corrective actions.

Action: Publish NUREG summarizing results.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 08/01/93

Resources: 0.0

Lead: Rathbun

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 05

Source Code: N Document No.: 001 Doc. Date: 09/08/92

Document: Memo on Medical Management Plan

Description: Human Factors studies
Teletherapy, Brachytherapy, high dose rate
Conduct human factors study. Determine utility of risk analysis techniques.

Action: Issue NUREG CR summarizing results of HF studies.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 09/30/93

Resources: 0.0

Lead: Kauffman

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 06

Source Code: A Document No.: 001 Doc. Date: 09/08/92

Document: Memo on Medical Management Plan

Description: Reassessment of training & experience criteria and preceptoring process for physician authorized users by Visiting Medical Fellow.

Action: Evaluate need to revise training & experience criteria in Part 35 & need to revise preceptoring process.

Notes: Action incorporates recommendations from ACMUI (Item #18) to revise 35.920 & 35.930 and to revise preceptor process.

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2: RM
Category 3: RG

DUE DATE: 09/30/94

Resources: 0.0

Lead: Glenn

Support: X, G, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track
Number: 07

Source Code: N Document No.: 002 Doc. Date:

Document: Medical Issues Paper (MIP)

Description: Evaluate Part 35
Prescriptive vs. performance based regs. & deregulations
Regulations will be reviewed to determine if need to amend to allow greater flexibility.

Action: Review Part 35 to determine if revision is needed to provide greater flexibility.

Notes:

PRIORITY: L

ACTION NO.:

Category 1: O
Category 2: RM
Category 3: LG

DUE DATE: 12/30/94

Resources: 0.0

Lead: Glenn

Support: X, R, A

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 08

Source Code: N Document No.: 002 Doc. Date:

Document: Medical Issues Paper (MIP)

Description: Part 35
Evaluate need for training & experience requirements for supervised individuals.

Action: Evaluate Part 35 requirements for supervision, training, & experience. Determine if revision is necessary.

Notes:

PRIORITY: L

ACTION NO.:

Category 1: O
Category 2: RM
Category 3: PO

DUE DATE: 12/30/94

Resources: 0.0

Lead: Glenn

Support: S, A, X

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 09

Source Code: N Document No.: 002 Doc. Date:

Document: Medical Issues Paper (MIP)

Description: Inspection/Enforcement guidance for QM Rule. Issue guidance for performance-based inspections of QM programs.

Action: Issue revised TI & field notes for QM program inspections. (Completed 4/5/93) Issue Enforcement Guidance Memorandum (Completed 4/30/93)

Notes:

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2: PO
Category 3: EG

DUE DATE: 05/15/93

Resources: 0.0

Lead: Glenn

Support: L, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 10

Source Code: N Document No.: 002 Doc. Date:

Document: Medical Issues Paper (MIP)

Description: Licensing Guidance
Complete SRP for Type A Broad Scope (updating P&GD).
Submit revision to RG 10.5 for Broad Scope to Research.

Action: Complete SRP & submit revised Reg Guide for Broad Scope to Research.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: LG
Category 2: RG
Category 3:

DUE DATE: 05/30/93

Resources: 0.0

Lead: Glenn

Support: X, R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track
Number: 11

Source Code: N Document No.: 002 Doc. Date:

Document: Medical Issues Paper (MIP)

Description: Abnormal Occurrence (AO) Reporting Criteria
Review and revise AO reporting criteria.

Action: Prepare Commission Paper on revision of AO reporting criteria to specifically address misadministrations. (Comp.)

Notes: Incorporates OGC recommendation in Item #38. Staff has prepared a Commission Paper recommending AO Reporting Criteria for misadministrations apd this paper is currently with EDO for review.

PRIORITY: H

ACTION NO.:

Category 1: PO
Category 2: RG
Category 3:

DUE DATE: 04/30/93

Resources: 0.0

Lead: Jordan

Support: N, R, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 12

Source Code: N Document No : 002 Doc. Date:

Document: Medical Issues Paper (MIP)

Description: Part 35 Rulemaking on Admin of Byproduct Material to Pregnant and Breastfeeding Women.

Action: Revise Part 35 to address need for licensees to determine pregnancy or nursing status of patients prior to administration.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: RM
Category 2:
Category 3:

DUE DATE: 11/30/93

Resources: 0.0

Lead: Bahadur

Support: N, G, P

Contract ($): 0

MASTER AGENDA: Medical Prpgram Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 13

Source Code: A Document No.: 007 Doc. Date: 07/13/92

Document: ACMUI Minutes

Description: NRC should prepare syllabus that can serve as basis for didactic basic radiation safety training of physicians for licensure.

Action: Evaluate need for syllabus.

Notes:

PRIORITY: L

ACTION NO.:

Category 1: RG
Category 2:
Category 3:

DUE DATE: 12/30/94

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 14

Source Code: A Document No.: 009 Doc. Date: 11/05/92

Document: ACMUI Minutes

Description: NRC should fund a national study of the impact of regulation on all uses of byproduct material in medicine. Study should be conducted by a University of neutral professional group.

Action: Evaluate for inclusion in Regulatory Impact Survey.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 09/30/93

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 15

Source Code: A Document No.: 009 Doc. Date: 11/05/92

Document: ACMUI Minutes

Description: NRC should explore substitution of voluntary accreditation by professional organizations for some of the NRC inspection processes.

Action: OGC to prepare legal analysis of substitution.
Staff will evaluate feasibility of substitution of ACNP, ACR processes in Commission paper with recommendations.

Notes: Incorporates ACNP recommendation (Item #23) and ACR recommendation (Item #24).

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2: PO
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Glenn

Support: G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 16

Source Code: A Document No.: 009 Doc. Date: 11/05/92

Document: ACMUI Minutes

Description: NRC should establish testing process for physicians & RSOs to evaluate competence.

Action: Evaluate feasibility of developing testing process.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: PO
Category 2:
Category 3:

DUE DATE: 06/30/94

Resources: 0.0

Lead: Glenn

Support: N, G, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 17

Source Code: A Document No.: 009 Doc. Date: 11/05/92

Document: ACMUI Minutes

Description: NRC should monitor adequacy of radiation safety component of consultant rad. safety courses, residency programs, & board certification courses.

Action: Evaluate feasibility of monitoring adequacy of programs.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 06/30/94

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 18

Source Code: A Document No.: 009 Doc. Date: 11/05/92

Document: ACMUI Minutes

Description: NRC should revise 10 CFR 35.920 (Trng. for Imaging and Localization) & 10CFR 35.930 (Training for Therapeutic Use of Radiopharmaceuticals to more appropriately reflect knowledge base.

Action: Incorporated into action for Item #6.

Notes:

PRIORITY:

ACTION NO.:

Category 1: O
Category 2: RM
Category 3:

DUE DATE:

Resources: 0.0

Lead: Glenn

Support: X, G, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 19

Source Code: A Document No.: 009 Doc. Date: 11/05/92

Document: ACMUI Minutes

Description: NRC should expand address list for mailings to include not only licensee mgt. but also RSO & Chief of Service for each authorized user, and use newsletters of professional societies for informing users.

Action: Evaluate feasibility/cost of expanding LTS.

Notes:

PRIORITY: L

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 20

Source Code: N Document No.: 011 Doc. Date: 03/10/93

Document: SOW QM Plan Review

Description: Contractor to review QM plans for adequacy & develop tracking system showing status of reviews.

Action: Award Contract.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 06/01/93

Resources: 700.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 21

Source Code: N Document No.: 011 Doc. Date: 03/10/93

Document: SOW QM Plan Review

Description: Contractor to review QM plans for adequacy & develop tracking system showing status of reviews.

Action: Complete review and issue final report.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 06/01/94

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 22

Source Code: N Document No.: 013 Doc. Date: 03/12/93

Document: Response to COMSECY-93-004

Description: Upon Commission approval of SOW, prepare proposal package for National Academy of Sciences' Review of Medical Program.

Action: Prepare proposal package for NAS Review of Medical Program.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2: PO
Category 3:

DUE DATE: 06/15/93

Resources: 0.0

Lead: Rathbun

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 23

Source Code: N Document No.: 017 Doc. Date: 11/09/92

Document: Summ. Pub. Mtg. QM

Description: ACNP expressed a desire to explore possibility of NRC recognition of its Practice Audit Program as alternative to inspection of the audit program.

Action: Incorporated into action for Item #15.

Notes:

PRIORITY:

Category 1: O
Category 2:
Category 3:

Lead: Glenn

Support:

ACTION NO.:

DUE DATE:

Resources: 0.0

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track
Number: 24

Source Code: O Document No.: 018 Doc. Date:

Document: Comm Paper QM/Misadministration

Description: American College of Radiology (ACR) expressed interest in discussions w/ NRC re: acceptance of a voluntary QA program.

Action: Incorporated into action for Item #15.

Notes:

PRIORITY:

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 25

Source Code: N Document No.: 020 Doc. Date: 05/13/92

Document: SECY 92-175: Annual Report

Description: Provide training to Regions on QM rule.

Action: Followup training for Regions on interim final field notes & temporary instruction.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE: 07/30/93

Resources: 0.0

Lead: Glenn

Support: L, G, H

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 26

Source Code: N Document No.: 020 Doc. Date: 05/13/92

Document: SECY 92-175: Annual Report

Description: Revise Part 35 and Reg Guide 10.8 to address remote afterloader brachytherapy & gamma stereotactic surgery.

Action: Issue user need memo to RES to revise Part 35 & Reg. Guide 10.8. Complete QA plan for Gamma Knife (#2) remote afterloaders (#3). Complete Human Factors studies. (#5). Use input to develop user need memo.

Notes: See related IIT item #55.

PRIORITY: H

ACTION NO.:

Category 1: RM
Category 2: RG
Category 3:

DUE DATE: 03/01/94

Resources: 0.0

Lead: Glenn

Support: X, P, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 27

Source Code: M Document No.: 020 Doc. Date: 05/13/92

Document: SECY 92-175: Annual Report

Description: ACNP/SNM petition of 2/10/92 contends current fee schedule adversely impacts medical licensees. (Completed 4/9/93)

Action: Prepare comments for LFMB.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 04/06/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 28

Source Code: N Document No.: 021 Doc. Date: 01/19/93

Document: SECY 93-007: Aspects of Med. Prog. RE: Misad.

Description: Consider issue of expanded NRC followup of patients subject to misadministrations; also refer to external group for consideration.

Action: Refer to external group for consideration.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: PO
Category 2: O
Category 3: RM

DUE DATE: 07/15/93

Resources: 0.0

Lead: Glenn

Support: G, D

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 29

Source Code: N Document No.: 021 Doc. Date: 01/19/93

Document: SECY 93-007: Aspects of Med. Prog. re: Misad.

Description: Conduct analysis of adequacy of NRC, FDA & Agreement States review of medical devices.

Action: Incorporate into related IIT Item #57.

Notes:

PRIORITY:

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Haughney

Support: P, S, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 30

Source Code: N Document No.: 021 Doc. Date: 01/19/93

Document: SECY 93-007: Aspects of Med. Prog. re: Misad.

Description: Reassess base civil penalties regarding deterrence.

Action: Evaluate need to increase base civil penalties.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2: PO
Category 3: EG

DUE DATE: 07/30/93

Resources: 0.0

Lead: Lieberman

Support: N

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 31

Source Code: C Document No.: 022 Doc. Date: 06/23/92

Document: SRM: Annual Medical Briefing

Description: Analysis on whether the evolution of the NRCs medical use program has been consistent with the 1979 statement of Comm. policy & whether any changes to the policy are warranted.

Action: Incorporate into medical management plan; also refer to external group Work into all rulemakings a statement of consistency.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 07/30/93

Resources: 0.0

Lead: Glenn

Support: X

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 32

Source Code: C Document No.: 023 Doc. Date: 12/21/92

Document: COMIS-92-026: Review of Medical Program

Description: Nominate senior NRC manager to perform mgt. review of existing medical program. Coordinate review with med. management plan & focus on whether program is being efficiently implemented.

Action: Perform management review of existing medical program.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 06/15/93

Resources: 0.0

Lead: Paperiello

Support: N, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 33

Source Code: N Document No.: 024 Doc. Date: 08/10/92

Document: Memo on Developing NUREG for RSOs

Description: Duties, functions, & responsibilities of an RSO for a licensed program need to be defined.

Action: Develop and publish NUREG for RSOs.

Notes: See related IIT Item #51.

PRIORITY: M

ACTION NO.:

Category 1: RG
Category 2:
Category 3:

DUE DATE: 06/30/94

Resources: 0.0

Lead: Glenn/Combs

Support: R, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 34

Source Code: N Document No.: 028 Doc. Date: 02/09/92

Document: P&G Directive on Supervision

Description: Formal guidance will be developed for routine and reactive inspections re: QM Rule.

Action: Finalize field notes & inspection procedure.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE: 12/31/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 35

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Develop guidance document on licensee responsibilities in event of misadministration. Include reporting, patient notification and investigation of event.

Action: Develop Information Notice.

Notes: Also see related IIT Item #55.

PRIORITY: H

ACTION NO.:

Category 1: RG
Category 2:
Category 3:

DUE DATE: 05/30/93

Resources: 0.0

Lead: Glenn

Support: G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 36

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Evaluate need for specific requirement, together with implementing guidance, imposing a duty on licensee to inform other persons exposed as a result of misadministration.

Action: Incorporate into action for IIT Item #54.

Notes:

PRIORITY:

ACTION NO.:

Category 1: O
Category 2: LG
Category 3:

DUE DATE:

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 37

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Develop criteria for when a misadministration warrants an AIT or IIT.

Action: Revise directive 8.3, NRC Incident Investigation Program to include criteria that may warrant AIT or IIT for misadministrations.

Notes: Will include examples.

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 10/01/93

Resources: 0.0

Lead: Jordan

Support: N,O, Regns

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 38

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Develop criteria for misadministrations that are abnormal occurrences, identifying what efforts NRC will use to meet its statutory reporting obligations under Section 208.

Action: Incorporate into action for Item #11.

Notes:

PRIORITY:

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Jordan

Support: N

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 39

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Develop criteria for following up with patients suffering acute present injury or possibility of radiation illness after misadministrations.

Action: Incorporate into revision to MC 1360 in Item #41.

Notes:

PRIORITY:

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 40

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Review draft & final guidance on QM Program to ensure inspectors properly emphasize licensee's duty to report misadministrations to patients & referring physicians.

Action: Incorporated into guidance development addressed in Items #09 and #34.

Notes:

PRIORITY:

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Glenn

Support: R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 41

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Review existing policies/requirements/guidance on proper role of medical consultants in assisting NRC.

Action: Revise MC 1360 to address issue and provide guidance to regional and HQ staff.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE: 05/30/93

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 42

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Review existing policies/requirements on retention of records including what records must be retained and for how long.

Action: Meet with OGC and request legal analysis of basis for longer retention.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 06/30/93

Lead: Combs

Resources: 0.0

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 43

Source Code: G Document No.: 029 Doc. Date: 02/12/93

Document: OGC Memo on Misadministrations

Description: Staff may wish to review for each misadministration classified as an AO, licensee's written reports to patients versus those submitted to NRC.

Action: Prepare memo based on meeting with OGC & OI to discuss feasibility. (Completed by memo of 4/19/93; see Item #70)

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 04/15/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 44

Source Code: G Document No.: 030 Doc. Date: 02/17/93

Document: OGC Memo on IIT Report

Description: Review guidance & guides on Brachytherapy in light of IIT findings re: Indiana, PA incident.

Action: Issue bulletin to all HDR users (Completed 4/20/93); consider longer term actions consistent with IIT memo.

Notes: See related actions under IIT Item #55.

PRIORITY: H

ACTION NO.:

Category 1: LG
Category 2:
Category 3:

DUE DATE: 04/15/93

Resources: 0.0

Lead: Glenn

Support: G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 45

Source Code: G Document No.: 030 Doc. Date: 02/17/93

Document: OGC Memo on IIT Report

Description: Revise licensing guidance in FC 86-4 which appears to be outdated & not well integrated with NRC regulations.

Action: Issue revised FC 86-4.

Notes: See related actions under IIT Item #55.

PRIORITY: H

ACTION NO.:

Category 1: LG
Category 2:
Category 3:

DUE DATE: 06/01/93

Resources: 0.0

Lead: Glenn

Support: R, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 46

Source Code: G Document No.: 030 Doc. Date: 02/17/93

Document: OGC Memo on IIT Report

Description: Revise insp. guidance to address HDR Brachytherapy & cover multiple places of use, situations where RSO can't promptly respond & license amendments greatly expanding licensee's operations scope.

Action: Issue TI for inspection of HDR afterloaders.

Notes: See related IIT Items #59 and #60 for multiple locations & changes in scope.

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE: 06/30/93

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 47

Source Code: G Document No.: 030 Doc. Date: 02/17/93

Document: OGC Memo on IIT Report

Description: Consider revisions to Part 35 to eliminate list of sources in 35.400; clarify which provisions apply to HDRs & to LDRs; & need for additional provisions for either.

Action: Incorporate into action for Item #26.

Notes:

PRIORITY:

ACTION NO.:

Category 1: O
Category 2: RM
Category 3:

DUE DATE:

Resources: 0.0

Lead: Glenn

Support: X, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 48

Source Code: N Document No.: 031 Doc. Date:

Document: Outline for Paperiello Review

Description: Revise licensing guidance for HDR Brachytherapy & review existing guidance for all other therapy to ensure it is current.

Action: Evaluate resource requirements/availability for all other guidance.

Notes: See related IIT Item #55 for HDRs.

PRIORITY: H

ACTION NO.:

Category 1: LG
Category 2:
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 49

Source Code: N Document No.: 031 Doc. Date:

Document: Outline for Paperiello Review

Description: Regional inspectors need an inspection procedure for the followup of misadministration reports & other radiation therapy events.

Action: Incorporated into Items #9 and #34.

Notes:

PRIORITY:

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 50

Source Code: N Document No.: 031 Doc. Date:

Document: Outline for Paperiello Review

Description: Ensure availability of current inspection guidance for HDR Brachytherapy & all other therapy programs.

Action: Incorporate into related IIT Item #55.

Notes:

PRIORITY:

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE:

Resources: 0.0

Lead: Combs

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 51

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Evaluate need to further define RSO & authorized user responsibilities. Issue new or revised guidance, as appropriate.

Action: Evaluate need for guidance for authorized users.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2: RG
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 52

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Evaluate performance & design of PrimAlert-10 ARMs. Take followup action as required to resolve issue of spurious alarms & need for confidence by users.

Action: Write to manufacturer for evaluation of nonionizing RF's or EMF's re: Spurious alarms. Issue TI to Regions to include in routine inspection program.

Notes: If appropriate, issue Information Notice to licensees.

PRIORITY: M

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 06/30/93

Resources: 0.0

Lead: Combs

Support: R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 53

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Evaluate NRC's process for: a) assessing exposure & consequences, & b) notifying individuals & authorities following following elevated exposure to the public. Issue guidance as appropriate.

Action: Incorporate IIT lessons and issue Manual Chapter.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE: 06/30/93

Resources: 0.0

Lead: Combs

Support: R, G, NRR

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 54

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Evaluate need to further define licensee responsibility for assessing radiation exposure & notifying members of public & authorities. Issue guidance as appropriate.

Action: Staff will evaluate need for rule change.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2: RM
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Combs

Support: R, G, NRR

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 55

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Eval. need to update & integrate existing requirements. Guidance & inspection procedures for HDR Afterloaders. Issue new or revised requirements & guidance, as appropriate.

Action: Incorporate results of guidance & research into user need memo to RES to revise Part 35.

Notes: Related actions include: Issue bulletin to Remote Afterloader users (4/30/93); Revise P&GD 86-4 (6/30/93); Issue TI for HDR inspections (7/30/93); Evaluate QA and HF studies (9/30/93).

PRIORITY: H

ACTION NO.:

Category 1: LG
Category 2: IG
Category 3: RM

DUE DATE: 03/01/94

Resources: 0.0

Lead: Glenn

Support: R, X

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 56

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Eval. performance based approach vs schooling or certifications to verify adequate rad. safety knowledge of HDR afterloader users. Issue new or revised requirements or guidance, as appropriate.

Action: Conduct evaluation, discuss with ACMUI and provide recommendations.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2: RM
Category 3: LG

DUE DATE: 03/01/94

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 57

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Eval licsng interface & juris. betw NRC/FDA & states/agreement states for sealed sources & devices including licensee requirements for design reviews & QA/QC. Execute new or revised agreements, as appropriate.

Action: Coordinate with FDA/Agreement States.
Prepare evaluation of interface & jurisdiction issues.
Develop Commission paper.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2: PO
Category 3:

DUE DATE: 06/01/94

Resources: 0.0

Lead: Glenn/Haugh.

Support: P, S, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 58

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Revise inspection guidance to include a provision to trigger consideration for licensees whose programs have significantly changed.

Action: Develop criteria and prepare P&G Directive.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: LG
Category 2: IG
Category 3:

DUE DATE: 09/30/93

Resources: 0.0

Lead: Combs

Support: R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 59

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: For near term & where indicated, conduct inspections of licensees whose programs have significantly expanded or changed since last routine inspection.

Action: Issue memo to Regions to poll licensing staff & perform inspections, as necessary. Complete inspections.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: IG
Category 2:
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Combs

Support: R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 60

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Eval need for assisting nonradioactive waste processing industry in establishing guidance for detecting & obtaining expert assistance for handling of radioactive materials. Assist in developing guidance.

Action: Develop pamphlet for non-radiation waste processors, incorporating IIT lessons.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 10/30/93

Resources: 0.0

Lead: Austin/Combs

Support: P, R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 61

Source Code: I Document No.: 032 Doc. Date: 03/12/93

Document: IIT Action Memo

Description: Evaluate Southwest Research's final report on source wire failure and document findings.

Action: Evaluate and make recommendations.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2:
Category 3:

DUE DATE: 10/30/93

Resources: 0.0

Lead: Haughney

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 62

Source Code: M Document No.: Doc. Date: 06/01/91

Document: Marcus Petition

Description: Inconsistency between revised Part 20 Public Dose limits & Patient release criteria in 35.75 should be clarified (incorporate ACNP petition).

Action: Issue final rule revising Part 35.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: RM
Category 2:
Category 3:

DUE DATE: 01/01/94

Resources: 0.0

Lead: Cool

Support: N, P, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/12/93

Track Number: 63

Source Code: N Document No.: Doc. Date: 06/05/89

Document: ACNP/SNM Petition

Description: Continue to allow physician-directed departures from package inserts: extension of time period under interim final rule.

Action: Issue final rule, revising Part 35.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: RM
Category 2:
Category 3:

DUE DATE: 08/23/93

Resources: 0.0

Lead: Bahadur

Support: N, G, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 64

Source Code: M Document No.: Doc. Date: 06/05/89

Document: ACNP/SNM Petition

Description: Rev. Pt.35 to allow departures fr/pkg inserts create category of auth. nuc. pharm., allow physician authorized users & auth. nuc. pharm to compound radioactive drugs, allow research in human subjects...

Action: Issue final rule revising Parts 35, 32 and 30.

Notes:

PRIORITY: H

ACTION NO.:

Category 1: RM
Category 2:
Category 3:

DUE DATE: 02/28/94

Resources: 0.0

Lead: Bahadur

Support: N, G, P

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 65

Source Code: N Document No.: Doc. Date: 02/17/93

Document:

Description: Prepare P&GD on acceptable training and experience for physician-authorized users.

Action: Develop P&GD.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: LG
Category 2: PO
Category 3:

DUE DATE: 09/30/94

Resources: 0.0

Lead: Glenn

Support:

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 66

Source Code: N Document No.: Doc. Date: 12/09/92

Document:

Description: Review medical field notes, specifically Nuclear Medicine field notes (diagnostic component) to determine savings of time to divert to QM inspections. (IMAB 1149)

Action: Revise QM field notes & inspection guidance.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: IG
Category 2: EG
Category 3:

DUE DATE: 03/30/94

Resources: 0.0

Lead: Glenn/Combs

Support: R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 67

Source Code: C Document No.: Doc. Date: 06/25/91

Document: SRM Dated 06/19/91

Description: Provide Commission with assessment of the effectiveness of QM Rule at annual briefing 3 years after rule becomes effective.

Action: Gather data regarding implementation, monitor QM enforcement actions; evaluate need for comprehensive QM program.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: RG
Category 2: IG
Category 3: EG

DUE DATE: 04/30/95

Resources: 0.0

Lead: Bahadur/Glen

Support: N, R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 68

Source Code: R Document No.: NA Doc. Date: 02/17/93

Document: IMAB 974

Description: Prepare Policy & Guidance on Temporary exemptions for Emergency/Humanitarian Reasons.

Action: P&GD would provide Region with guidance on how to proceed in granting temporary exemptions from the regulations for emergency/humanitarian reasons, such as patient release outside of criteria in 35.75.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: LG
Category 2:
Category 3:

DUE DATE: 09/30/93

Resources: 0.0

Lead: Glenn

Support: R, G

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 69

Source Code: N Document No.: NA Doc. Date: 12/19/91

Document:

Description: Prepare Policy & Guidance directive for master materials licensing/inspection manuals (IMAB 731).

Action: Prepare P&G Directive.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: LG
Category 2: IG
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Glenn

Support: R

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 70

Source Code: N Document No.: NA Doc. Date: 03/10/93

Document:

Description: Need for clarification of apparent weaknesses in 10CFR 35.33 regarding patient notification.

Action: Prepare memo to OGC requesting clarification of current rule language & whether additional rulemaking is needed. (Completed 4/19/93)

Notes:

PRIORITY: H

ACTION NO.:

Category 1: O
Category 2: PO
Category 3: RM

DUE DATE: 04/30/93

Resources: 0.0

Lead: Glenn

Support: G, H

Contract ($): 0

MASTER AGENDA: Medical Program Improvements
Source Document Record Format
Printed on 05/13/93

Track Number: 71

Source Code: N Document No.: NA Doc. Date: 08/05/92

Document:

Description: Develop inspection manual guidance regarding verification of newly-licensed activities & supervision under 35.25 guidance Coordinate with IMAB.

Action: Update IP 87100 and Manual Chapter 2800.

Notes:

PRIORITY: M

ACTION NO.:

Category 1: IG
Category 2: LG
Category 3:

DUE DATE: 12/30/93

Resources: 0.0

Lead: Combs

Support: N, G, L

Contract ($): 0