AA73-1
PDR
D.9

For HQ & regional staff
Spring 1984
Slide show

# THE PROPOSED REVISION OF 10 CFR PART 35

BACKGROUND

REGULATION

SYSTEM AT WORK

IMPACT ON NRC

WHAT'S WRONG NOW

INCOMPLETE

INFLEXIBLE

UNREADABLE



R 1

INCOMPLETE - REQUIREMENTS ARE IN

REGULATIONS
LICENSE CONDITIONS
ORDERS
REG GUIDES

INFLEXIBLE - MINOR PROGRAM
CHANGES MUST BE APPROVED
BY NRC

UNREADABLE

| | |
|---|---|
| COMIC BOOK | 92 |
| READERS DIGEST | 65 |
| TIME MAGAZINE | 52 |
| PROPOSED PART 35 | 26 |
| IRS CODE | -6 |
| CURRENT PART 35 | -56 |

## SCOPE OF PROJECT

CLEAN UP REGS

STREAMLINE LICENSING

## SOURCE OF PROPOSED REGS

CURRENT PART 35

RG 10.8 AND TELE NUREG

STD LIC CONDITIONS

## SUGGESTED LICENSING SYSTEM

NRC REVIEWS APPLICATION

WOULD NOT REVIEW USER CREDENTIALS OR PROCEDURES

WOULD REVIEW AMNTS, EQPT

COMMISSION RESPONSE

ENDORSED SUGGESTED REGULATORY TEXT
DIRECTED REVIEW OF USER CREDENTIALS
DIRECTED REVIEW OF OPERATING PROCEDURES

STAFF RESPONSE

MINOR REVISIGN OF REGULATORY TEXT
REVIEW USER CREDENTIALS ON SUPP. A & B
REVIEW PROCEDURES SIMILAR TO NRC-313M p.2
REVIEW EQUIPMENT AND FACILITY

THE PROPOSED REVISION OF
10 CFR PART 35

BACKGROUND
REGULATION
SYSTEM AT WORK
IMPACT ON NRC

DRAFTING POLICY

REGULATIONS FOR "REASONABLE MAN"

USE S OF C TO CLARIFY, CLOSE LOOPHOLES

justify by calculation or credible scenarios

"good practice, everyone does it, to not require would be a step backwards" are inadequate.

OUTLINE OF PROPOSED PART 35

| SUBPART | TOPIC |
|---|---|
| A | GENERAL INFORMATION |
| B | ADMINISTRATIVE REQUIREMENTS |
| C | TECHNICAL REQUIREMENTS |
| D | GENERAL/I UPTAKE |
| E | II/III IMAGING |
| F | IV/V DRUG THERAPY |
| G | VI BRACHYTHERAPY |
| H | DIAGNOSTIC SEALED SOURCES |
| I | TELETHERAPY |
| J | TRAINING |
| K | ENFORCEMENT |

Act says "must have license" Hearing would recognize others who actually handle the matl "under supervision of lic. mgt."

A - GENERAL INFORMATION

LICENSE REQUIRED - MD v TECH

APPLICATION/ISSUANCE

AMENDMENTS

EXEMPTIONS - NO SLC'S

## B - ADMINISTRATIVE REQUIREMENTS

ALARA PROGRAM AT INSTITUTIONS ONLY

MOBILE SERVICE

MISADMINISTRATION - STATUS QUO

SUPERVISION CLARIFIED

## C - TECHNICAL REQUIREMENTS

DOSE CALIBRATOR CALIBRATION

SURVEY METER CALIBRATION

SYRINGE AND VIAL SHIELDS AND LABELS

DAILY AND WEEKLY SURVEYS

PATIENT RELEASE AT 6MR/HR OR 30MCI

MOBILE SERVICE - UNIT DOSAGES ONLY

STORAGE OF VOLATILES AND GASES

DECAY-IN-STORAGE

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| G | VI BRACHYTHERAPY |
| H | DIAGNOSTIC SEALED SOURCES |
| I | TELETHERAPY |
| J | TRAINING |
| K | ENFORCEMENT |

D - UPTAKE (GENERAL/I)

LL SURVEY METER

E - IMAGING (II/III)

Mo BREAKTHROUGH CHANGED

GASES AND AEROSOLS CONTROLLED

LL AND HL SURVEY METERS

F - DRUG THERAPY (IV/V)

SAFETY PRECAUTIONS

LL AND HL SURVEY METERS

G - BRACHYTHERAPY

RELEASE OF PATIENTS

INVENTORY LOG

SAFETY PRECAUTIONS

HL SURVEY METER

H - DIAGNOSTIC SEALED SOURCES (NEW)

LIXISCOPE

BONE MINERAL ANALYZER

LL OR HL METER AVAILABLE

## I - TELETHERAPY

LL OR HL SURVEY METER

AAPM PETITION

INTERLOCKS ADDED TO SPOT CHECK

## OUTLINE OF PROPOSED PART 35

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|---|---|
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| B | ADMINISTRATIVE REQUIREMENTS |
| C | TECHNICAL REQUIREMENTS |
| D | GENERAL/I UPTAKE |
| E | II/III IMAGING |
| F | IV/V DRUG THERAPY |
| G | VI BRACHYTHERAPY |
| H | DIAGNOSTIC SEALED SOURCES |
| I | TELETHERAPY |
| J | TRAINING |
| K | ENFORCEMENT |

## J - TRAINING

REQUIRED TO OPERATE LEGALLY

ADDED RSO, QTCE

UPTAKE AND DIAG SLD SC NEW

OTHERS FROM FRN

K - ENFORCEMENT

INJUNCTION OR COURT ORDER

CIVIL PENALTY

FINE OR IMPRISONMENT

THE PROPOSED REVISION OF
10 CFR PART 35

BACKGROUND

REGULATION

SYSTEM AT WORK

IMPACT ON NRC

IN-VITRO

RETAIN FORM NRC-483

GRANDFATHER 35.14c USERS IN 31.11

## THE NEW SYSTEM AT WORK

APPLICATIONS

AMENDMENTS AND RENEWALS

INSPECTIONS

## APPLICATIONS

REVIEW APPLICATION AS TODAY PER SRP

T & E, EQUIPMENT, AND FACILITY

TELEPHONE OR WRITTEN DEFICIENCY LTR

ISSUE LICENSE

## LICENSE

FOR AUTHORIZATION

NOT DAY-TO-DAY REGULATION

## LICENSE

NAME AND ADDRESS

BPM AND QUANTITIES

USERS:
- JOE SMITH - RSO
- BILL JONES - QTCE
- JOHN BLACK, MD - SUBPARTS D, E
- ED BROWN, MD - SUBPARTS D, E
- JILL TRUMBLE, DDS - LIXISCOPE ONLY
- MARY MAYER, MD - SUBPART I

EXPIRATION DATE

NO "IAW" OR SLC

## AMENDMENTS

NEW USERS - REVIEW T & E

NEW TYPE - AS NEW APPL PER SRP

NEW LOCATION - NEW PACKAGE

NEW METHOD - HQ WILL ISSUE FRN

RENEWALS - REFERENCE PREVIOUS PACKAGE

## INSPECTIONS

USE REGS, NOT APPLICATION

## CITATIONS IN 1982

60% WERE BASED ON REGS (729 OF 1240)

97% STAND ON DRAFT REGS (1201 OF 1240)

THE PROPOSED REVISION OF
10 CFR PART 35

BACKGROUND
REGULATION
SYSTEM AT WORK
IMPACT ON NRC

IMPACT ON NRC

APPLICATION REVIEW
LICENSE INSPECTION
NRC OPERATIONS

APPLICATION REVIEW

APPL, WITH PROCEDURES, SIMILAR TO CURRENT
STD REVIEW PLAN BASED ON REGS
ONE PAGE LICENSE
NO "IN ACCORDANCE WITH" OR STD LIC CONDITIONS

## LICENSE INSPECTION

SAME ABILITY TO CITE

CITE AGAINST REGS, NOT APPLICATION

SMALLER RECORDS FILES ON SITE

MORE OPERATIONS REVIEW, LESS RECORDS REVIEW

## NRC OPERATIONS

QUICKER LICENSING AND INSPECTION

INTER-REGIONAL UNIFORMITY

FEWER AMENDMENTS

MINIMAL STAFF RETRAINING

Talk Slow.
Don't get excited

McElroy Jan 85

Draft for
Commission Mtg

There are some disputes
on the

PROPOSED REVISION OF

PART 35

~~MEDICAL USE OF BYPRODUCT MATERIAL~~ Requirements

10 minutes
where we are
where we would
like to go

Industry Overview

Current Regulatory Policy

Why Change

The Proposal

Impact

Disputes

| LICENSEES | NRC | AgS |
|---|---|---|
| Hospitals | 2200 | 3700 |
| Physicians | 300 | 1100 |

25% of NRC licenses

For most

TYPES OF USE

Diagnostic pharmaceuticals all US

.01-30 mCi dosage; 10-15 million/yr

small amts short $T_{1/2}$

Therapeutic pharmaceuticals

10-200 mCi dosage; 10,000/yr

Brachytherapy sealed sources

70 mCi implant for 3 days; 10,000/yr

Cobalt teletherapy

5000 rads over 4 weeks; 200,000/yr

DOSES

Workers

90% get less than 0.5 rem/yr

Patients under presc. of spec. trad physicians

Diagnostic--1 rem whole body

Therapeutic--5000 rads to tumor

To understand...

## CURRENT POLICY

### Licensing

| | |
|---|---|
| Apply 10-50pp | list materials; describe training and experience, procedures (or promise to follow Regulatory Guide), facility and equipment 1580 fee |
| Deficiency Letter | clarify, or strengthen the program |
| Licensure | lists address, users, materials, "for medical use," "In accordance with application" |

### Amendments

| | |
|---|---|
| Major Changes | submit amendment request, describe change $230 fee new users, RSO, min. inventory |
| Minor Changes | submit amendment request, describe change what, where waste room update ept |
| Renewal | reference application, describe changes assign a task |

### Inspections

| | |
|---|---|
| Inspection | watch workers, review records, measure dose rates 9/80 ~3yr |
| Legal Basis for Citations | Application, Parts 20, 19, 35, and 30 Most citations |

## PROBLEMS WITH CURRENT POLICY

Requirements are scattered

- Regulations
- Regulatory Guides
- License Conditions
- Branch Policy

Unreadable

| | Index* |
|---|---|
| Comic Book | 92 |
| Reader's Digest | 65 |
| Time Magazine | 52 |
| Proposed Part 35 | 26 |
| IRS Code | -6 |
| Current Part 35 | -56 |

*Index algorithm and examples are from How to Write Plain English, by Rudolph Flesch

Inflexible

Use "in accordance with" application

1800 amendments each year

WHY CHANGE

Evolution has slowed

New developments will be variations on current themes

same radn safety problems

Increase agency efficiency through standardization

Free licensing staff for more important matters

Allow licensees flexibility to select most cost-effective way to meet NRC safety objectives

## REQUIREMENTS IN THE PROPOSAL

Current

- Part 35
- Regulatory Guides
- License Conditions
- Branch Policy

no sig changes in licensee's day-to-day opn

Added

- NRC reviews teletherapy expert credentials
- Notify NRC if a physician leaves
- Licensee must issue a clear statement of authority to Radiation Safety Officer
- Teletherapy room safety check
- Training standards for uptake, dilution, and excretion users

Changed

- Licensee can make minor program changes
- Operational definition of worker supervision
- Alternative patient release standard
- New "type of use" group--diagnostic sealed sources
- AAPM petition
- Alternative teletherapy calibration procedure

| | CURRENT POLICY | PROPOSAL |
|---|---|---|
| | **Licensing** | |
| Apply | list materials; describe training and experience, procedures (or promise to follow Regulatory Guide), facility and equipment | no change |
| Deficiency Letter | clarify, or strengthen the program | no change |
| Licensure | lists address, users, materials, "for medical use," "In accordance with application" | delete "In accordance with application" |
| | **Amendments** | |
| Major Changes | submit amendment request, describe change | listed on reg no change |
| Minor Changes | submit amendment request, describe change | In-house review reg'd by reg New RG has check list |
| Renewal | reference application, describe changes | no change |
| | **Inspections** | |
| Inspection | watch workers, review records, measure dose rates | no change |
| Legal Basis for Citations | Application, Parts 20, 19, 35, and 30 | Parts 35, 20, 19, and 30 |

PROCEDURES

not mechanical proc. that req. meticulous att to detail

Applicant can reference a Regulatory Guide procedure or submit his own for NRC review

There are management ~~procedures~~ and technical ~~procedures~~ guidance

Examples of each follow

Elements that are underlined were included in the proposed regulation

From Regulatory Guide 10.8, Guide for the Preparation of Applications for Medical Programs. October 1980.

Charter
Duties
Administrative matter

## APPENDIX B

## MEDICAL ISOTOPES COMMITTEE*

**Responsibility**

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license. (1)

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license. (2)

**Duties**

The committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments. (3)

2. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license. (4)

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19. (1)

4. Review and approve all requests for use of radioactive material within the institution. (5)

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures. (6)

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and the adequacy of the institution's management control system. (7)

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program. (8)

8. Maintain written records of all committee meetings, actions, recommendations, and decisions. (9)

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license. (10)

**Meeting Frequency**

The medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter. (11)

*A rule is expected in 1981 that would change the name, composition, and functions of this committee.

The underlined requirements are included in the proposed revision at the section noted.

1. § 35.31(b)(2)(x)
2. § 35.31(a)
3. § 35.31(b)(2)(xi)
4. § 35.32(b)(2)
5. § 35.32(b)(3)
6. § 35.33
7. § 35.32(b)(7)
8. § 35.33
9. § 35.32(a)(5)
10. § 35.17 and § 35.36
11. § 35.32(a)(2)

From Regulatory Guide 10.8, Guide for the Preparation of Applications for Medical Programs. October 1980.

## APPENDIX I

## AREA SURVEY PROCEDURES

where frequency action levels

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.* (1) (2)

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly. (3)

4. The weekly ahd monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr. (4)

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 $cm^2$ for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement. (5)

5. A permanent record will be kept of all survey results, including negative results. The record will include: (6)

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies. (6)

   b. Name of person conducting the survey. (6)

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc. (6)

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action). (6)

   e. Detected contamination levels, keyed to locations on drawing. (6)

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments. (7)

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 $cm^2$. ← RSO decides Tc should decay

*For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

The underlined requirements are included in the proposed revision at the section noted.

1. § 35.70(a)
2. § 35.31(b)
3. § 35.70(b)
4. § 35.70(c)
5. § 35.70(f)
6. § 35.70(h)
7. § 35.31(b)(2)(vi)

mgt decisions that are not of sig. radn concern who does which instr

IMPACTS

Safety and Effectiveness

No increase or decrease in worker or public dose

perception of hazard is ill-founded; more control than morphine, other BNDD

Efficiency

reduce paper flow

NRC--reduces licensing staff time; savings could be used for increased inspection or other materials problems

Licensees--reduces queue and review time and fees; allows Radiation Safety Officer to do his job

conduct business

Concerning

Cost

NRC

$94,000 once to train staff;

save $60,000 each year from decreased time needed to prepare for inspections

51 pp total
36 pp inspectable

Licensees

$1.4 M/yr increase due to new requirements

save $0.4 M/yr due to licensing change

DISPUTES

except for "minor change" clause, unan. agrmnt.

Technical disputes among regulators

Major--all resolved NRC and AgS endorse

Minor--RIII wants formal ALARA program for private practitioners

Licensing and amendments

RIII--review changes that decrease program effectiveness

AgS--"Permitting licensees to make changes is an unwarranted relaxation of regulatory control. . . this puts too much control in licensees' hands. . ." not compatibility, but perceive pressure

what's major & minor? - major is reg'd amn. minor is any other

Inspection

AgS--Places too much burden on inspectors given time constraints and inspection frequency

Physician training and experience credentials

No major changes here; suggestion for an alternative standard is being handled separately by MSB (Cerrill & cardiologists)

Misadministration

Industry wants reporting requirements taken out; Commissioners directed retention (SECY-82-388)

For Commission Mtg

SECY-84-485

PROPOSED REVISION OF

10 CFR PART 35

MEDICAL USE OF BYPRODUCT MATERIAL

## LICENSEES

| | NRC | Agreement States |
|---|---|---|
| Hospitals | 2200 | 3700 |
| Physicians | 300 | 1100 |

## TYPES OF USE

- Diagnostic Radiopharmaceuticals

  .01-30 mCi dosage; 10-15 million each year

- Therapeutic Radiopharmaceuticals

  10-200 mCi dosage; 10,000 each year

- Brachytherapy Sealed Sources

  70 mCi implant for 3 days; 10,000 each year

- Cobalt Teletherapy

  5000 rads over 4 weeks; 200,000 each year

## PROBLEMS WITH CURRENT RULES AND GUIDANCE

- Requirements are scattered
  - Regulations
  - Regulatory Guides
  - License Conditions
  - Branch Policy

- Unreadable due to many amendments

- Inflexible
  - Use "in accordance with application"
  - Requires 1800 amendments each year

| | CURRENT METHOD | PROPOSED METHOD |
|---|---|---|
| **Licensing** | | |
| Apply | List materials; describe training and experience, procedures (or promise to follow Regulatory Guide), facility and equipment | No Change |
| Deficiency Letter | Clarify or strengthen the program | No Change |
| Licensure | Lists address, users, materials, "for medical use," "In accordance with application" | Delete "In accordance with application" |
| **Amendments** | | |
| Major Changes | Submit amendment request, describe change | No Change |
| Minor Changes | Submit amendment request, describe change | In-House Review Replaces Agency Review |
| Renewal | Reference application, describe changes | No Change |
| **Inspections** | | |
| Inspection | Watch workers, review records, measure dose rates | No Change |
| Legal Basis for Citations | Application, Parts 20, 19, 35, and 30 | Parts 35, 20, 19, and 30 |

# SAMPLE MANAGEMENT PROCEDURE

## APPENDIX B*

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SAMPLE TECHNICAL PROCEDURE
**APPENDIX I***

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   b. Name of person conducting the survey. (6)

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4. § 35.70(c)
5. § 35.70(f)
6. § 35.70(h)
7. § 35.31(b)(2)(vi)

*From Regulatory Guide 10.8, Guide for the Preparation of Applications for Medical Programs. October 1980.

IMPACTS

- Safety and Effectiveness

  No increase or decrease in worker or public dose

- Efficiency

  NRC - Reduces licensing staff time; savings could be used for increased inspection or other materials problems.

  Licensees - Reduces queue and review time and fees; allows Radiation Safety Officer to do his job.

ISSUES

- Technical disputes with the revision among regulators and licensees

  Major - None

  Minor - A few editorial changes and changes in equipment requirements.

- Authorization to make minor changes

  Agreement States - "Permitting licensees to make changes is an unwarranted relaxation of regulatory control....This puts too much control in licensees' hands....Many procedures cannot be reviewed in the field because of time constraints and inspection frequency...."