



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

Howard Community Hospital  
ATTN: Melinda Showalter, R.N.  
Director, Oncology Services  
3500 S. La Fountain St.  
Kokomo, IN 46901

Dear Ms. Showalter:

This refers to the routine safety inspection conducted by Mr. S. J. Mulay of this office from October 28, 1994 through November 14, 1994, of activities authorized by NRC Byproduct Material License No. 13-13028-01, and to the discussion of our findings with members of your staff at the conclusion of the inspection.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspector examined actions taken regarding violations found during our July 1992 inspection. We have no further questions regarding these matters.

No violations of NRC requirements were identified during the course of this inspection.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter will be placed in the NRC Public Document Room.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

A handwritten signature in cursive script, appearing to read "B. J. Holt".

B. J. Holt, Chief  
Nuclear Materials Inspection  
Section 1

License No. 13-13028-01  
Docket No. 030-00205

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ATTACHMENT A

QUALITY MANAGEMENT PROGRAM (QMP)

QM FIELD NOTES

1. GENERAL

- A. Facility name(s): Hawthorn Community Hospital
- B. License number(s): 13-13028-cl
- C. Docket number(s): 030-00205
- D. Last inspection date(s): 7/14/92
- E. Current inspection date(s): 10/28/94 - 11/10/94
- F. Most recent QMP and certification received by NRC [35.32(e), (f)(2)] Date: 6/29/94

2. PREPARATION

- A. Be familiar with the submitted QMP and any modifications in preparation for inspection of the licensee's implemented QMP. Familiarization should focus upon awareness of the submitted program in order to compare the written program with the program as implemented.

3. MODALITIES

- A. Identify licensee procedures and attach appropriate inspection module(s):

Module:

- 1. NaI I-125 or I-131 > 30  $\mu$ Ci and/or Therapeutic radiopharmaceutical other than NaI ( ) Y ( ) N
- 2. High-Dose-Rate Remote Afterloading Brachytherapy ( ) Y ( ) N
- 3. All Other Brachytherapy ( ) Y ( ) N
- 4. Strontium-90 eye applicator ( ) Y ( ) N
- 5. Teletherapy ( ) Y ( ) N
- 6. Gamma Stereotactic Radiosurgery  Y ( ) N
- 7. Event (misadministration or other) ( ) Y ( ) N

4. SAMPLING (Inspector random sample of each modality)

Total Written Directives

Minimum Target Sample

- 1 to 5 All
- 5 to 100 5
- > 100 5%

	<u>Total Written Dir.</u>	<u>Target Sample</u>	<u>Number Reviewed</u>
1. NaI I-125 or I-131 > 30 $\mu$ Ci	_____	_____	_____
2. Therapeutic Radiopharmaceutical other than NaI	_____	_____	_____
3. HDR remote afterloading brachytherapy	_____	_____	_____
4. Other brachytherapy	_____	_____	_____
5. Sr-90 eye applicator	_____	_____	_____
6. Teletherapy	_____	_____	_____
7. Gamma Stereotactic Radiosurgery	<u>78</u>	<u>5</u>	<u>8</u>

If two (2) or more written directives are incomplete or missing, the review must be expanded to assess whether this is an isolated occurrence or represents a substantial failure of the QMP.

MODULE 5  
TELE THERAPY

1. SUPERVISION

- A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)]  Y ( ) N  
List individual(s) found to be inadequately trained:

2. OBJECTIVE 1

Number Missed

- A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]  Y ( ) N \_\_\_\_\_
- B. Written directives contain required information, total dose, dose per fraction, site, & overall treatment period [35.2]  Y ( ) N \_\_\_\_\_
- C. Exceptions to written directives documented [footnote to 35.32(a)(1)]  N/A
1. Written revisions ( ) Y ( ) N \_\_\_\_\_
2. Oral revisions ( ) Y ( ) N \_\_\_\_\_
3. Oral directives ( ) Y ( ) N \_\_\_\_\_

Remarks:

3. OBJECTIVE 2

- A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]  Y ( ) N \_\_\_\_\_

Remarks:

4. OBJECTIVE 3

- A. Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives [35.32(a)(3)]  Y ( ) N \_\_\_\_\_
- B. Procedures may include: (not requirements)
1. Check of dose calculations by an authorized user or a qualified person under supervision

- of an authorized user who whenever possible did not make the original calculations  Y ( ) N
2. Performing acceptance testing (based on licensee's specific needs and applications) on each treatment planning or dose calculating computer program that could be used for dose calculations ( ) Y ( ) N
3. Determining transmission factors for beam modifying devices before first use and after replacement of the source ( ) Y ( ) N
4. Output measurements for treatment parameters not addressed in the most recent full calibration ( ) Y ( ) N
5. Checking dose calculations administration in fractions (procedure should include consideration of number of fractions and specified time within which the check should be performed) ( ) Y ( ) N
6. Other, describe: ( ) Y ( ) N

Remarks:

5. OBJECTIVE 4

A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]  Y ( ) N \_\_\_\_\_

B. Procedures may include: (not requirements)

1. Plan of treatment prepared in accordance with the written directive  Y ( ) N
2. Person administering treatment confirms the written directive and plan of treatment. At a minimum, the verification of treatment site and dose per fraction  Y ( ) N
3. Other, describe:

B. Record of each administration or fraction maintained in auditable form  Y ( ) N \_\_\_\_\_

6. OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)]  Y ( ) N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] ( ) Y ( ) N - N/A  
 Dates of events:

- 2. Recordable events identified by inspector [35.32(c), 35.2] ( ) Y (X) N
- 3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) ( ) Y (X) N
- B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] (X) Y ( ) N
- C. Procedures may include: (not requirements)
  - 1. Assemble relevant facts including cause ( ) Y ( ) N
  - 2. Identify corrective action to prevent recurrence ( ) Y ( ) N
  - 3. Retain a record of items 1 and 2 ( ) Y ( ) N
- D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N
- E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] ( ) Y (X) N

Remarks:

7. PERIODIC REVIEWS OF THE QMP

- A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] (X) Y ( ) N  
Date of last review: 12/21/93
- B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] (X) Y ( ) N  
  
The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.
- C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the events were isolated ( ) Y ( ) N - N/A
- D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] (X) Y ( ) N
- E. Based on the evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] (X) Y ( ) N
- F. Modifications sent to NRC within 30 days [35.32(e)] (X) Y ( ) N ( ) N/A

- G. Records of reviews including the evaluation and findings maintained for at least 3 years [35.32(b)(3)]  Y ( ) N

Remarks:

8. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

Interviews with Administrative Staff members demonstrated adequate knowledge of QMP procedures. No patients are treated without a signed and dated written protocol <sup>by</sup> an authorized person. Of the 8 patient files reviewed, all <sup>written protocols</sup> appeared to contain the information required by 35.32.

9. Time spent completing this module: 3.5 hours