

SAINT
JOSEPH
MERCY
HEALTH SYSTEM

A Member of Mercy Health Services



PUBLIC/PDR
030-01997
ST. JOSEPH MERCY HOSPITAL

5301 East Huron River Drive
P.O. Box 995
Ann Arbor, MI 48106-0995
Telephone (313) 712-3456

1/21/98

U.S.N.R.C.
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

LICENSE: (21-00943-03)

DEAR SIRS:

ENCLOSED ARE QMP PROGRAM REVISIONS REQUIRED FOR HDR
OPERATION. THESE ARE IN ADDITION TO OUR LICENSE REQUEST
WHICH WAS MADE SEPARATELY.

SINCERELY,

Rayma L. Bilicki, RSO

RAYMA BILICKI, RSO

[Signature]

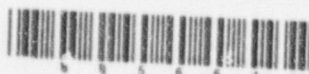
[Signature]

RECEIVED

JAN 26 1998

REGION III

040019
9802040228 980121
PDR ADOCK 03001997
C PDR



JAN 26 1998

ADOCK

Pm: 1-22-98

31 ML
DH

REQUIRED QUALITY MANAGEMENT
POLICIES FOR HIGH DOSE RATE REMOTE AFTERLOADING

1. BEFORE ADMINISTRATION OF A BRACHYTHERAPY DOSE FROM A HIGH DOSE RATE REMOTE AFTERLOADING UNIT IT IS REQUIRED THAT AN AUTHORIZED USER MUST SIGN AND DATE A WRITTEN DIRECTIVE. (THE ONLY EXCEPTION WOULD BE TO ALLOW AN ORAL DIRECTIVE IF EMERGENT NATURE OF THE PATIENTS MEDICAL CONDITION WAS SUCH THAT THE DELAY TO PROVIDE A WRITTEN DIRECTIVE WOULD JEOPARDIZE THE PATIENTS HEALTH. IF THIS IS THE CASE THE ORAL DIRECTIVE WILL BE DOCUMENTED IMMEDIATELY IN THE PATIENTS RECORD AND THE WRITTEN DIRECTIVE PREPARED WITHIN 24 HOURS OF THE ORAL DIRECTIVE.)

2. AT LEAST TWO METHODS MUST BE USED TO VERIFY THE HDR PATIENTS IDENTITY. METHOD ONE SHOULD BE TO ASK THE PATIENTS NAME AND CONFIRM THE PATIENTS NAME AND IN ADDITION AT LEAST ONE OF THE FOLLOWING ITEMS THEN COMPARED WITH THE PATIENTS RECORD.

- A. BIRTH DATE
- B. ADDRESS
- C. SOCIAL SECURITY NUMBER
- D. FACE PHOTO
- E. ID BADGE
- F. ID CARD
- G. SIGNATURE
- H. MEDICAL INSURANCE CARD

3. BEFORE ADMINISTRATION THE PERSON ADMINISTERING THE TREATMENT WILL VERIFY THAT THE FOLLOWING DETAILS OF THE TREATMENT ARE IN ACCORDANCE WITH THE WRITTEN DIRECTIVE AND PLAN OF THE TREATMENT.

- A. ISOTOPE
- B. TREATMENT SITE
- C. TOTAL DOSE

4. IF ANY INDIVIDUAL WORKING ON THIS CASE DOES HAS ANY DOUBTS OR CONCERNS ABOUT HOW TO CARRY OUT THE WRITTEN DIRECTIVE THAT INDIVIDUAL MUST STOP AND SEEK DIRECTION BEFORE CONTINUING ON WITH ANY PROCEDURE.

5. RADIOGRAPHS, 3D ULTRASOUND OR OTHER COMPARABLE IMAGES WILL BE USED AS THE BASIS FOR VERIFYING THE POSITION OF THE NON RADIOACTIVE DUMMY SOURCE LOCATIONS AND CALCULATING THE ADMINISTERED DOSE BEFORE INSERTING THE ACTUAL SEALED SOURCES.

6. CALCULATIONS MUST BE CHECKED BEFORE ANY DOSE IS ADMINISTERED. THE CHECKING INDIVIDUAL WILL BE ONE OF THE FOLLOWING.

- A. RADIATION ONCOLOGY PHYSICIAN
- B. RADIATION THERAPY PHYSICIST
- C. DOSIMETRIST
- D. RADIATION THERAPY TECHNOLOGIST

WHENEVER POSSIBLE THE INDIVIDUAL WHO DID THE CALCULATIONS WILL NOT DO THE CHECKING. CALCULATIONS CHECKS WILL INCLUDE:

- A. COMPUTER GENERATED DOSE CALCULATIONS-EXAMINING THE COMPUTER PRINTOUT TO VERIFY THAT CORRECT INPUT DATA FOR THE PATIENT WERE USED
- B. COMPUTER GENERATED DOSE CALCULATIONS DATA FOR INPUT INTO THE BRACHYTHERAPY AFTERLOADING DEVICE-VERIFYING CHANNEL NUMBERS, TREATMENT TIMES AND SOURCE POSITIONS ARE CORRECT

7. THE AUTHORIZED USER AFTER ADMINISTERING THE BRACHYTHERAPY TREATMENT WILL DATE, AND SIGN OR INITIAL A WRITTEN RECORD OF THE CALCULATED ADMINISTERED DOSE IN THE PATIENTS CHART OR OTHER APPROPRIATE RECORD.

8. IF THE AUTHORIZED USER DETERMINED THAT DELAYING TREATMENT IN ORDER TO PERFORM THE CHECKS OF DOSE CALCULATIONS WOULD JEOPARDIZE THE PATIENTS HEALTH BECAUSE OF THE EMERGENT NATURE OF THE PATIENTS MEDICAL CONDITION THE TREATMENT MAY BE GIVEN AND CHECKS OF CALCULATIONS THEN SHOULD BE PERFORMED WITHIN 2 WORKING DAYS OF THE TREATMENT.

9. ACCEPTANCE TESTING BY A QUALIFIED PERSON (e.g., A TELETHERAPY PHYSICIST) WILL BE DONE ON EACH TREATMENT PLANNING OR DOSE CALCULATING COMPUTER PROGRAM THAT COULD BE USED FOR BRACHYTHERAPY DOSE CALCULATIONS WHEN USING THE HIGH DOSE RATE AFTERLOADING DEVICES. ACCEPTANCE TESTING WILL BE PERFORMED BEFORE THE FIRST USE OF A TREATMENT PLANNING OR DOSE CALCULATING COMPUTER PROGRAM FOR BRACHYTHERAPY DOSE CALCULATIONS WHEN USING HIGH DOSE RATE REMOTE AFTERLOADING DEVICES. (ALL EVALUATIONS WILL BE DONE BASED ON OUR NEEDS AND APPLICATIONS)

10. ALL HDR CASES WILL BE REVIEWED BY PHYSICIANS AT THEIR WEEKLY MEETINGS. THE CHARTS WILL BE REVIEWED TO DETERMINE IF IN EACH CASE THE TREATMENT WAS DELIVERED IN ACCORDANCE WITH THE WRITTEN DIRECTIVE.

- A. PROPER ISOTOPE
- B. PROPER DOSE
- C. PROPER SITE

IF ANY RECORDABLE EVENTS OR MISADMINISTRATIONS ARE IDENTIFIED THE WILL BE HANDLED AS REQUIRED IN 10.CFR.32.110. IN ADDITION ANY SUCH INCIDENTS WILL BE REPORTED TO THE DEPARTMENT QA COMMITTEE AND DISCUSSED AND INCLUDED IN THE MINUTES OF THE NEXT QA MEETING. PARTICULAR WEIGHT WOULD BE GIVEN TO THE CAUSE OF EACH DEVIATION AND THE ACTION REQUIRED TO PREVENT RECURRENCE. ACTIONS OF THE REVIEW GROUPS MAY INCLUDE NEW OR REVISED POLICIES, NEW OR REVISED PROCEDURES, ADDITIONAL TRAINING OR INCREASED SUPERVISORY REVIEW OF WORK.

ANNUAL REVIEW WOULD THEN INVOLVE:

- A: REVIEW OF THE QA COMMITTEE MINUTES AND ANY CASES

IDENTIFIED AS RECORDABLE EVENTS OR
MISADMINISTRATIONS.

- B: AN ADDITIONAL REVIEW OF APPROXIMATELY 5 % OF THE
TOTAL CASES WITH AN EYE TOWARD GENERAL COMPLIANCE
AND SAFETY.
- C: A REVIEW OF THE QMP'S POLICIES AND PROCEDURES
TO IDENTIFY IF THE PROGRAM IS STILL EFFECTIVE OR
WHAT MUST BE DONE TO MAKE IT EFFECTIVE.