

DL-040396-02

Centra Health, Inc.

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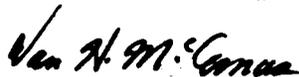
Nuclear Regulatory Commission
Attn.: David Collins
101 Marietta Street, NW.
Suite 2900
Atlanta, GA. 30323-0199

April 3, 1996

SUBJECT: Amendment of Teletherapy License # 45-10542-02

Enclosed you will find an amendment request for Virginia Baptist Hospital's Cobalt-60 Teletherapy License #45-10542-02. This is in response to your letter dated March 1, 1996 (one-time extension of license) and our renewal application dated August 30, 1995. Please amend our license to read: The Radiation Safety Officer (RSO) for this license is Van H. McComas, MS or in his absence, Larry H. Redmond, MD., alternate RSO, (reference NRC License # 45-02207-01). In addition, I am submitting a copy of our ALARA Program and Quality Management Program for your review and records. If you have any questions please call me at 804-947-7406 or my FAX number is 804-947-7400. Thank you.

Sincerely,



Van H. McComas, MS., D.A.B.R.
Medical Physicist / Teletherapy Physicist

257029

ALARA Program

1. Management Commitment:

a. We, the management of this Medical Center are committed to the program described herein for keeping individual and collective doses to radiation or radioactive material as low as reasonably achievable (ALARA). In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include the Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of the radiation doses received by all involved individuals.

2. Radiation Safety Committee:

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposures ALARA.

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(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedure and that individuals and collective doses will be ALARA.

b. Delegation of Authority

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of the ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedure as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposures as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, Authorized Users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual, Semi-Annual and Quarterly Review

(1) **Annual review of the radiation safety program.** The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) **Quarterly review of occupational exposures.** The RSO will review at least quarterly the external radiation exposures of Authorized Users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program and will report to the RSC.

(3) Semi-annual review of records of radiation level survey. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous two quarters and will report to the RSC.

Table 1

Investigational Levels
(mrem per calendar quarter)

Area of Body	Level I	Level II
Whole body, head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
Hands and forearms; feet, ankles	1,875	5,625
Skin of whole body	750	2,250

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform worker's supervisors of ALARA program efforts.

(2) The RSO will ensure that Authorized Users, workers, and auxiliary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures. Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will receive and evaluate the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices. The RSO will ensure investigation of all known instances of deviation from good ALARA practices and, if possible, will determine the cause. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Exposures

(1) The Authorized User will consult with, and receive the approval of, the RSO and/ or RSC during the planning stage before using radioactive materials for a new method of use.

(2) The Authorized User will evaluate all methods of use before using radioactive materials to ensure that exposure will be kept ALARA. This may be enhanced by using trial runs.

b. Authorized User's Responsibility to Supervised Individuals.

(1) The Authorized User will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The Authorized User will ensure that supervised individuals who are subject to occupational radiation exposures are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Exposure

a. Worker will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Worker will know what recourses are available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures.

This institution hereby establishes investigational levels for occupational external radiation dose which, when exceeded, will initiate review or investigation by the RSC and/ or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures" or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by §20.401 of 10 CFR Part 20. The following actions will be taken at the investigational levels as stated in Table 1.:

a. **Personnel dose less than Investigational Level I:** Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. **Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II:** The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the review at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of other performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. **Personnel dose equal to or greater than Investigational Level II:** The RSO will investigate in a timely manner the cause of all personnel dose equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any action taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. **Re-establishment of Investigational Level II to a level above that listed in Table 1** In cases where a worker's or a group of workers' doses need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for and will approve all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph 6.c. above will be followed.

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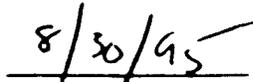
7. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.



Signature

Thomas C. Jividen
President, Virginia Baptist Hospital



Date

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Quality Management Program

QUALITY MANAGEMENT PROGRAM*Virginia Baptist Hospital***Purpose:**

The following program has been established to ensure that the teletherapy procedures carried out at this facility are of the highest quality and in compliance with Title 10, Code of Federal Regulations, Part 35.32 (10 CFR 35.32).

Policy:

Prior to an administration of any teletherapy dose as listed under 10 CFR 35.600, a written directive must be prepared, dated and signed by an authorized user:

Definitions:

Misadministration means a teletherapy dose:

- Involving the wrong patient, wrong mode of treatment, or wrong treatment site, or
- When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose, or
- When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose, or
- When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

Prescribed dosage for teletherapy means the total dose and dose per fraction as documented in the written directive.

Written directive for teletherapy means the total dose, dose per fraction, treatment site, and overall treatment period.

Recordable event means a teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

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Procedures:

1. Prior to the administration of a teletherapy dose, a written directive must be prepared, dated and signed by an authorized user. The authorized user will approve a plan of treatment that provides sufficient information and direction to meet the objective of the written directive. In addition, the treatment site and the dose per fraction shall be confirmed by the person administering the teletherapy dose to verify agreement with the written directive.

2. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

3. Also, a written revision to an existing written directive may be made for any therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the teletherapy dose.

4. If, because of the emergent nature of the patient's condition, a delay in treatment due to performing checks of dose calculations or teletherapy output would jeopardize the patient's health, the prescribed treatment shall be provided without the checks, provided that the authorized user makes a note of this determination in the records of the calculations. The checks shall be performed within two working days of the completion of the treatment.

5. Prior to each administration of a teletherapy dose, the patient's identity must be verified as the individual named in the written directive by more than one method. This may be done by asking the patient's name and confirming it, and by at least one of the following methods; comparison with corresponding information in the patient's record: birth date, address, social security number, or signature; comparison with the name on the Patient's ID bracelet or hospital card, the name on the patient's medical insurance card, or a photograph taken of the patient's face for ID purposes.

6. The final plans of treatment and related calculations for the teletherapy dose must be reviewed by the authorized user or a qualified person under the supervision of the authorized user to ensure that they are in accordance with the respective written directive.

7. If at any time a worker needs guidance or is unclear as to how a written directive is to be carried out, they should seek advice from the authorized user rather than continuing with a procedure.

8. All unintended deviations from a written directive must be identified and evaluated, and appropriate actions taken, (see misadministration and recordable events).

9. After the administration of the teletherapy dose fraction, a qualified person under the supervision of an authorized user, shall make, date, and sign or initial a written record in the patient's chart or in another appropriate record that contains, for each treatment field, the treatment time, dose administered, and the cumulative dose administered.

10. Weekly chart checks shall be performed by a qualified person under the supervision of an authorized user to detect mistakes (arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administration from all treatment fields or in connection with any changes in the written directive or plan of treatment.

11. If the prescribed dose is to be administered in more than three fractions, the dose calculations shall be checked within three working days after administering the first teletherapy fractional dose. An authorized user or a qualified person under the supervision of an authorized user who did not make the original calculations shall check the dose calculation. If the prescribed dose is to be in three fractions or less, a check of the calculations shall be performed before the first treatment on the teletherapy unit.

12. If a full calibration measurement that resulted from replacement of the source, or whenever a spot-check measurement indicates that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions shall be performed. The independent check shall be performed within 30 days following such full calibration measurements. The independent check shall be performed by the teletherapy physicist using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within 5 percent.

13. A full calibration shall be performed after a replacement source has been installed and annually thereafter in accordance with 10 CFR 35.632.

14. Physical measurements of the teletherapy output under applicable conditions prior to the administration of the first teletherapy fractional dose shall be made if the patient's plan of treatment includes field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or the transmission factors for beam-modifying devices not measured in the most recent full calibration.

15. The teletherapy physicist shall perform acceptance testing on each treatment planning or dose calculation computer program that will be used for teletherapy dose calculations before the first use of a treatment planning or dose calculating computer program for teletherapy dose calculations and after a full calibration when the calibration was performed before the first medical use of the teletherapy unit, after replacement of the source, or when a spot check measurement indicates the output differs by more than 5 percent of the output obtained at the last full calibration corrected mathematically for radioactive decay

16. An annual review of the quality management program will be performed by the Radiation Safety Officer, Teletherapy Physicist, or his designee. The RSO, Teletherapy Physicist, or designee should not review their own work independently. If this is not possible, they should review the program with another person as a team. The review shall include an evaluation of a representative sample of patient administrations based on the 10% table of lot tolerance percent defects in 10 CFR 32.110 (b)(8). If a misadministration or recordable event is uncovered during this review, the number of cases reviewed shall be expanded in accordance with Regulatory Guide 8.33. The review shall also include an evaluation of all recordable events, and all misadministration to verify compliance with all aspects of the quality management program. For each case reviewed, the reviewer(s) should determine whether the administered teletherapy dose was in accordance with the written directive. A record of each review, including the evaluations and findings of the review, will be reported to the Radiation Safety Committee and will be kept in an audible form for three years. The report should identify deviations from the written directive, the cause of each deviation, and the action(s) required to prevent recurrence. The action(s) may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work. Each of these reviews will be evaluated by the Radiation Safety Committee to determine the effectiveness of the quality management program and, if required, the committee will make modifications to meet the objectives of the program.

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17. **Recordable events**, within 30 days after discovery of a recordable event, the Radiation Safety Officer shall:

- Assemble the relevant facts including the cause;
- Identify what, if any, corrective action is required to prevent recurrence; and
- Make an audible record of the relevant facts and what corrective action, if any, was taken. This record shall be retained for three years.

18. **Misadministration**, the Radiation Safety Officer or his designee will immediately follow the steps outline in 10 CFR 35.33 and make all appropriate reports and notification as well as advising administration of the incident.

19. Modifications to the Quality Management Program will be submitted to the Nuclear Regulatory Commission within 30 days after the modification has been made as required by 10 CFR 35.32 (e).

Effective Date of Implementation: January 20, 1992

Revised: Sept. 2, 1995

Van H. McCombs
Radiation Safety Officer

Sept. 2, 1995
Date

[Signature]
President, Virginia Baptist Hospital

8/30/95
Date