

Weber

February 21, 1994

John A. Grobe, Chief
Nuclear Materials Inspection
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

License No. 21-01103-04
Docket No. 030-02003

Subject: "Reply to a Notice of Violation" dated 1/21/94

Dear Mr. Grobe:

This letter is in response to the Notice of Violation dated 1/21/94 in the above referenced matter in which you requested for the "violation" and "area of concern" the reason for the violation, corrective steps and the date when full compliance will be achieved.

Violation: 10 CFR 35.60(b) (Section 9 and 21) requires that, to identify its contents, a licensee conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, and that the label show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

Reason for Violation: The licensee did not label syringes containing radiopharmaceuticals to show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

Corrective Steps: Syringes containing radiopharmaceuticals for **all patients** are now being labeled. A meeting has been conducted with our technologists informing them of this violation. Special labels have been ordered to apply to the syringes.

Date of Full Compliance: 1/7/94

Area of Concern: The effectiveness of the newly appointed Radiation Safety Officer at Flint Osteopathic Campus.

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PDR ADOCK 03002003
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Corrective Steps: Dr. Prasad will meet bi-monthly with Flint Osteopathic Campus personnel to discuss incidents and incident reports as well as to advise on safety issues. These meetings will increase communication between staff and the Radiation Safety Officer. Primary responsibilities of the Radiation Safety Officer will reside with Dr. Prasad, although Dr. Frederick will continue to perform as an alternate.

In addition, Genesys Regional Medical Center will file an amendment to their license identifying Genesys' St. Joseph Campus and Genesys' Flint Osteopathic Campus as separate licensees under Genesys Regional Medical Center. Each campus will have an identified "Radiation Safety Officer" and Radiation Safety Committee to increase the effectiveness of the management oversight at both campuses.

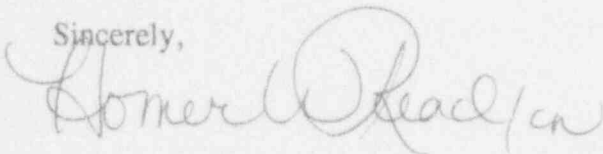
Date of Full Compliance: 1/7/94

Relative to minor suggestions made by the inspector regarding the QMP records, please find attached a revised copy of the Quality Management Program, based on our periodic review pertaining to the brachy therapy program.

Also, as required by 10 CFR 20.1302, DAC measurements performed at both Flint Osteopathic Campus and St. Joseph Campus are forwarded at this time.

If you have any further questions concerning this matter, please feel free to contact me at 810/762-8599.

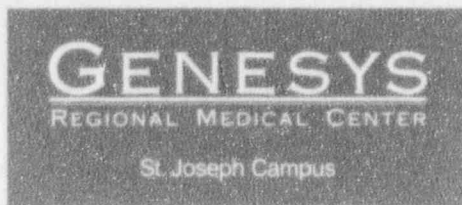
Sincerely,



Homer W. Read
Assistant to the
President

HWR/cmn

cc: Carnakanti Prasad, Ph.D.
Joseph Kyle
Mark Gentle



**BRACHYTHERAPY QUALITY MANAGEMENT
POLICIES AND PROCEDURES**

IMPLEMENTED: January 27, 1993
Medical License No. 21-01103-04

Objective

To provide high confidence that byproduct material will be administered as directed by the "authorized user".

1. It will henceforth be an established policy to have an authorized user date and sign a written directive prior to the administration of any brachytherapy dose.

a. If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an **oral** directive will be acceptable, provided that the information contained in the **oral** directive is documented in the patient's record and a written directive is prepared within 24 hours of the **oral** directive.

2. Prior to administering a brachytherapy dose the patient will be identified by more than one method as the individual referred to by the written directive.

- a. The patient shall be called by name.
- b. The patient shall be asked to spell their name.
- c. The patient shall be asked to state their birth date.
- d. The patient shall be asked to state their social security number.
- e. A photograph of the patient's face shall be checked.
- f. The in-patient's wrist band shall be checked.

3. If the information obtained from both of any two of these methods does not correspond to the information on the written directive, the brachytherapy dose shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

Before administering the brachytherapy dose, verify that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of sources, and source strengths should be confirmed to verify agreement with the written directive and plan of treatment.

4. Workers are instructed to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) should verify that the radioisotope, number of sources, source strengths, and, if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources.* The verification may be achieved by checking the color-coding of the sealed sources.

6. For temporary brachytherapy implants, radiographs of brachytherapy nonradioactive "dummy" sources in place of the radioactive sources will be used to calculate the exposure time (or, equivalently, the total dose). In some instances, however, "dummy" sources may not be substituted for radioactive sources in certain implant techniques where the actual sources are placed under anesthesia in the operating room (e.g., Cesium 137 needle implants in the tongue or other anatomical structures or organs.) Films of the radioactive source implant geometry will be obtained afterward in the radiation therapy simulator room, radiology, or in the operating room as deemed appropriate.

7. Radiographs or other comparable images of brachytherapy radioactive sources will be used to verify the position of permanently implanted radioactive sources, (e.g., Iodine 125 sealed sources used for interstitial applications), and for calculating the total dose to the area of interest.

8. After insertion of the temporary implant brachytherapy sources, the authorized user will record the actual loading sequence and sign or initial the patient's chart or other appropriate record.

9. After insertion of the permanent implant brachytherapy sources the authorized user will record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

10. Dose calculations will be checked before the total prescribed brachytherapy dose has been administered. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations. Manual dose calculations should be checked for:

*The term sealed sources includes wires and encapsulated sources.

10. Manual calculation check parameters (continued).

- (a). Arithmetic errors.
- (b). Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs.
- (c). Appropriate use of nomograms.
- (d). Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Manual calculation of a single key point will be compared to the computer-generated dose calculations to verify agreement to within ± 10 percent.

11. A written record will be placed in the patient's chart or other appropriate record of the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

12. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of completion of the brachytherapy treatment.

13. Acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program used for brachytherapy calculations will be done before the first use of a treatment planning computer for patient calculations.

14. Periodic reviews of all brachytherapy procedures will be done and reported annually as required by the QM program.

QUALITY MANAGEMENT REVIEW
Brachytherapy

Review Date: ___/___/___

Patient Name: _____

Number: _____

WRITTEN DIRECTIVE COMPLIANCE
(Y for yes, N for no)

Pre-implantation: ___ radioisotope
 ___ number of sources
 ___ source strength(s)

After implant
but prior to
completion of
the procedure: ___ radioisotope
 ___ treatment site
 ___ total source strength
 ___ exposure time (or total dose)

Comments: _____

Initials: _____

35.2 DEFINITIONS

Authorized user means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

Misadministration means the administration of:

- (1) A teletherapy radiation dose:
 - (a) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
 - (b) 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;
 - (c) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
 - (d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
- (2) A brachytherapy radiation dose:
 - (a) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
 - (b) Involving a sealed source that is leaking;
 - (c) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - (d) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

- (1) For teletherapy, the total dose and dose per fraction as documented in the written directive; or
- (2) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Recordable event means the administration of:

- (1) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or
- (2) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified for low-dose-rate brachytherapy, containing the following information:

- (1) For teletherapy: the treatment site, total dose, dose per fraction, and overall treatment period;
- (2) For low-dose-rate brachytherapy:
 - (a) Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - (b) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

St. Joeseph Hospital

Radiation Oncology Center

Brachy Therapy Implant Treatment Planning Summary Sheet

Date:

Patient Name :

Radio Nuclide: Cs-137

Treatment Site:

Type of Implant :

No. Of Sources Used :

Source Loading Sequence:

No. of Implant Hours: Time In: Time Out:

Dose Prescription:

Anatomic site & dose (cGy)

- | | |
|----|----|
| 1. | 4. |
| 2. | 5. |
| 3. | 6. |

Before Implant

After the Implant

Approved by:

Checked By :

Treatment

Planning done by:

BRACHYTHERAPY DOSE PRESCRIPTION

PATIENT NAME :

MED. REC. #

DIAGNOSIS:

TREATMENT SITE:

RADIO NUCLIDE: Cs-137 (Specify if any other)

DOSE PRESCRIPTION:

cGy

- @ 1. Vaginal Apex
- 2. Point A (Lt/Rt)
- 3. Point B (Lt//Rt)
- 4. Other Point

(Circle Which is applicable)

PHYSICIAN: DR. H. KIM / DR. D. OH

SIGNATURE:

DATE:

GENESYS

REGIONAL MEDICAL CENTER

St. Joseph Campus

WRITTEN DIRECTIVE

Any Radiopharmaceutical Therapy and/or any use of NaI-131 greater than 30 microcuries.

Patient Name _____

Patient Medical Record Number _____

Radiopharmaceutical _____

Activity Prescribed _____

Route of Administration _____

Procedure Desired _____

Authorized User: _____ Date: _____

Patient Identification (use at least two)

_____ Patient ID (Driver's License, Inpatient Wrist Band)

_____ Patient ID (Stated S.S., Patient Stated DOB)

_____ Lab (including possible pregnancy) checked

Administered By: _____ Date: _____

A:NUC.QA/WIRDI

QUALITY MANAGEMENT PROGRAM

St. Joseph Hospital

Implemented: 1/27/92

I. Objective

" . . . to provide high confidence that byproduct material will be administered as directed by the authorized user."

II. Responsibility, Authority and Audit

The responsibility and authority to establish and implement the Quality Management (QM) Program shall be given to Mark Gentle, Administrative Director of Radiology.

III. Elements for Medical Use - Radiopharmaceutical Therapies and Nal I-125 or I-131 > 30 uCi

- A. Prior to administration, a written directive will be prepared for:
1. any therapeutic administration of a radiopharmaceutical; and,
 2. any administration of NAL I-125 or I-131 greater than 30 uCi.
- With regard to diagnostic and therapeutic radiopharmaceuticals "A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:
- patient name
 - patient identification number, if available
 - radiopharmaceutical
 - dosage
 - route of administration
 - the type of procedure desired
- B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.
1. The patient shall be called by name.
 2. The patient shall be asked to spell their name.
 3. The patient shall be asked to state their birth date.
 4. The patient shall be asked to state their Social Security Number.
 5. The patient shall be asked for some identification such as driver's license.
 6. The inpatient's wristband shall be checked.
- If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the

radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

C. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologists shall read and understand the written directive.

The technologist shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure which requires a written directive shall not be initiated until a written protocol approved by an authorized user is available.

The technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them.

The protocols shall contain the following elements:

- pharmaceutical
- radionuclide
- routine dosage
- route of administration
- indications
- contraindications

Each change in protocol shall be approved by an authorized user before the change is implemented and before the change is incorporated into the procedure manual. Each technologist shall be instructed in the change before it is implemented or incorporated into the procedure manual.

D. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Upon identification of an unintended deviation, an investigation of the

incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of Part 35.

IV. Elements for Brachytherapy

- A. Prior to administration, a written directive will be prepared for:

Any brachytherapy radiation dose.

With regard to brachytherapy: A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

1. For high dose rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or,
 2. For all other brachytherapy:
 - a. Prior to implantation: the radioisotope, number of sources, and source strengths; and,
 - b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
- B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive.
- C. Each administration is in accordance with the written directive.
- D. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
- E. Final plans of treatment and related calculations for brachytherapy are in accordance with the written directive.

V. Elements for Teletherapy

- A. Prior to administration, a written directive will be prepared for:

Any teletherapy radiation dose.

With regard to teletherapy "A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

the total dose, dose per fraction, treatment site, and overall treatment period.

- B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive.
- C. Each administration is in accordance with the written directive.
- D. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
- E. Final plans of treatment and related calculations are in accordance with the respective directions.

ANNUAL REVIEW

The annual review shall be conducted by a member of management and the consulting medical physicist. The review shall be conducted at intervals not to exceed 12 months. The review shall determine the effectiveness of the Quality Management program. Areas identified as inadequate shall be modified to meet the objectives of 35.32(a).

Records of each review, including the evaluations and findings in an auditable form for three years.

Audit

Frequency: An audit of the Quality Management program shall be conducted at twelve (12) month intervals.

Responsibility: The audit shall be conducted by the Radiology Administrator/Office Manager and/or consulting medical physicist. If the audit is performed by the consulting physicist alone, management shall be briefed in writing of the findings.

Scope: The audit shall evaluate the following items:

1. The compliance rate of having written directives prior to administration of a radiopharmaceutical or radiation in those cases where written directives are required.
2. The content of the written directive is as required.
3. The instruction of the supervised individual(s) in the licensee's written Quality Management program and requirement of following the authorized user's instructions.
4. The methods of verifying the patient's identity by more than one method is performed as stated in the Quality Management

- program.
5. The compliance rate of verifying the patient's identity by more than one method.
 6. Radiopharmaceutical or radiation administrations are in accordance with the written directives.
 7. The compliance of the staff in identifying, evaluating, and taking appropriate corrective actions for unintended deviations from the written directive.
 8. The compliance with the requirement to respond to each recordable event.
 9. The compliance with the requirements to notify and report a misadministration.
 10. The compliance with the requirements to keep the appropriate records, including:
 - the annual reviews
 - the written directives
 - the radiopharmaceutical dosages
 - the recordable events
 - the misadministrations

Brachytherapy and Teletherapy Only

11. The final treatment plans and related calculations are in accordance with the written directive.

Method:

Items 1, 2, 3, 4, 5 and 6. Spot checks of the administration records for the previous twelve months shall be made at numerous intervals. A minimum of twenty (or if the volume is less than this, all) administrations records where written directives were required shall be reviewed for compliance.

Items 7, 8 and 9. Any unintended deviations discovered in the above review shall be tracked to determine if they were identified by staff. Records made by the staff shall be reviewed for thoroughness.

Item 10. Records made by the staff shall be reviewed for appropriateness. Current practices shall be reviewed with the staff to determine if the actions taken to address the unintended deviations are being followed.

Item 11 (Brachytherapy and Teletherapy Only). The final treatment plans shall be reviewed by Carnakanti Prasad, Ph.D.

Medical Physics Consultants, Inc.

VENTILATION EVALUATION

(Compliance with 10 CFR 35.205(e))

Date: 1/31/94

EXHAUST RATE

Total Measured Exhaust Rate = 1572 cfm

SUPPLY RATE

Total Measured Supply Rate = 1075 cfm

NET VENTILATION

Negative Pressure

497 cfm

Maximum Activity: 14000 μ Ci
Room Volume: 5600 ft³
(158575200 ml)

Medical Physics Consultants, Inc.

EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133 (Compliance with 10 CFR 35.205(c)(d))

1. Notify persons in the room that a spill (release) has occurred.
2. All persons should vacate the room at once.
3. Notify the RSO immediately.
4. Prevent entry into the room until the calculated evacuation time has occurred.

EVACUATION TIME: T = 1.5 MINUTES

Evacuation time (T) = $(-V/Q) \ln(CV/A)$ Where:

A = the highest activity of gas in a single container	14000 μ Ci
S = measured airflow supply rate from each vent	1075 cfm (30440775 ml/min)
Q = the total measured room air exhaust rate	1572 cfm (44514324 ml/min)
C = the maximum permissible air concentration in restricted areas	1.00×10^4 μ Ci/ml
V = the volume of the room	5600 ft ³ (158575200 ml)

Medical Physics Consultants, Inc.

AIRBORNE EFFLUENT CONCENTRATION

(Compliance with 10 CFR 20.1302)

Current Exhaust Rate: 1572 cfm

Total exhaust per week: 168 hr week = 4.49×10^{11} ml
40 hr week = 1.07×10^{11} ml

Inhalation occupational DAC limit (Restricted Areas): 1×10^{-4} $\mu\text{Ci/ml}$

Effluent concentration limit (Unrestricted Areas): 5×10^{-7} $\mu\text{Ci/ml}$

ENVIRONMENTAL RELEASE

Maximum allowed activity to be released per week:

$$A = (C)(V) \quad 5 \times 10^{-7} \mu\text{Ci/ml} \times 4.49 \times 10^{11} \text{ ml} = 224500 \mu\text{Ci}$$

Maximum activity to be used for patient studies per week is 140000 μCi

Assuming 20% of the activity used is released the maximum activity likely to be released per week is 28000 μCi

OCCUPATIONAL EXPOSURE

Assuming a patient volume of 10 patients per week and a maximum of 14 mCi/patient, the total activity released into the room is 28 mCi.

The concentration will be: $28000 \mu\text{Ci} / 1.07 \times 10^{11} = 2.62 \times 10^{-7} \mu\text{Ci/ml}$

This value is below the regulatory limit of $1 \times 10^{-4} \mu\text{Ci/ml}$ for restricted areas.

Medical Physics Consultants, Inc.

AIRBORNE EFFLUENT CONCENTRATION

(Compliance with 10 CFR 20.1302)

Current Exhaust Rate: 606 cfm

Total exhaust per week: 168 hr week = 1.73×10^{11} ml
40 hr week = 4.12×10^{10} ml

Inhalation occupational DAC limit (Restricted Areas): 1×10^{-4} $\mu\text{Ci/ml}$

Effluent concentration limit (Unrestricted Areas): 5×10^{-7} $\mu\text{Ci/ml}$

ENVIRONMENTAL RELEASE

Maximum allowed activity to be released per week:

$$A = (C)(V) \quad 5 \times 10^{-7} \mu\text{Ci/ml} \times 1.73 \times 10^{11} \text{ ml} = 86500 \mu\text{Ci}$$

Maximum activity to be used for patient studies per week is 140000 μCi

Assuming 20% of the activity used is released the maximum activity likely to be released per week is 28000 μCi

OCCUPATIONAL EXPOSURE

Assuming a patient volume of 10 patients per week and a maximum of 14 mCi/patient, the total activity released into the room is 28 mCi.

$$\text{The concentration will be: } 28000 \mu\text{Ci} / 4.12 \times 10^{10} = 6.79 \times 10^{-7} \mu\text{Ci/ml}$$

This value is below the regulatory limit of 1×10^{-4} $\mu\text{Ci/ml}$ for restricted areas.

Medical Physics Consultants, Inc.

VENTILATION EVALUATION

(Compliance with 10 CFR 35.205(e))

Date: 1/31/94

EXHAUST RATE

Total Measured Exhaust Rate = 606 cfm

SUPPLY RATE

Total Measured Supply Rate = 534 cfm

NET VENTILATION

Negative Pressure

72 cfm

Maximum Activity: 14000 μ Ci
Room Volume: 2446 ft³
(69320016 ml)

Medical Physics Consultants, Inc.

EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133 (Compliance with 10 CFR 35.205(c)(d))

1. Notify persons in the room that a spill (release) has occurred.
2. All persons should vacate the room at once.
3. Notify the RSO immediately.
4. Prevent entry into the room until the calculated evacuation time has occurred.

EVACUATION TIME: T = 3 MINUTES

Evacuation time (T) = $(-V/Q) \ln(CV/A)$ Where:

A = the highest activity of gas in a single container	14000 μ Ci
S = measured airflow supply rate from each vent	534 cfm (15121278 ml/min)
Q = the total measured room air exhaust rate	606 cfm (17160102 ml/min)
C = the maximum permissible air concentration in restricted areas	1.00×10^4 μ Ci/ml
V = the volume of the room,	2448 ft ³ (69320016 ml)