

COLUMBIA™
Chippenham Medical Center
Johnston-Willis Hospital

January 12, 1996

John M. Pelchat
U.S. Nuclear Regulatory Commission, Region II
Nuclear Materials Safety Section
101 Marietta Street, Suite 2900
Atlanta, Georgia 30323

RE: Amendment of Licenses 45-15249-01 and 45-02888-01

Dear Mr. Pelchat:

We would like to amend our material licenses to combine the two facility licenses into one. Attached is a check for \$430.00 to cover the fee specified in 10 CFR 170.31.

As of January 01, 1996, a single corporation was formed, Chippenham and Johnston-Willis Hospitals, Inc. which will d/b/a Chippenham Medical Center and Johnston-Willis Hospital. We now have a single Medicare number, 490012, and a single Tax ID number, 54-1779911. We will be surveyed by the Joint Commission on Accreditation of Healthcare Organization in 1996 as a single organization. We have a single Board of Directors with Dr. John L. Thornton as President, a single Chief of Staff, Dr. Barry W. Burkhardt, and a single Chief Executive Officer, Marilyn B. Tavenner.

The State of Virginia requires two hospital licenses (site specific), but we otherwise function as a single organization.

Ms. Lenna Deletis is presently the named RSO on the Chippenham License. We would like her to serve as the RSO for both campuses. Her present position requires her to be on both campuses daily and the closeness of the two facilities makes it easy for her to respond to issues at either campus in a very short period of time.

The named users on both licenses remain the same and all should be included on the combined license.

In order to provide standardized policies and procedures for both campuses, we propose the following documents in our Radiation Safety Program:

- ATT 7.1 Training (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 9.1 Calibration (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 9.2 Dose Calibrator (Johnston-Willis Hospital - Ministerial - Enclosed)

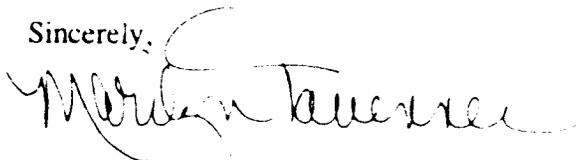
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- ATT 9.4 Monitoring (Johnston-Willis Hospital - Ministerial - Enclosed)
- ATT 9.6.1 Facilities (Johnston-Willis and Chippenham)
- ATT 10.1 Radiation Safety Committee (Johnston-Willis Hospital - Ministerial - Enclosed)
- ATT 10.2 ALARA program (Johnston-Willis and Chippenham - New - Enclosed)
- ATT 10.2.1 QMP Program (Johnston-Willis and Chippenham - New - Enclosed)
- ATT 10.3 Leak Testing (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.4 Rules of Use (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.5 Emergency Procedures (Chippenham Medical Center)
- ATT 10.6 Order/Receive (Johnston-Willis Hospital policy, July 24, 1990)
- ATT 10.7 Opening packages (Johnston-Willis Hospital - Ministerial - Enclosed)
- ATT 10.8 Unit Doses (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.9 Multidose Vial (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.10 Molybdenum (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.11 Implant Sources (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.12 Surveys (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.13 Air Concentrations (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.14 Radiopharmaceuticals (Chippenham Medical Center, Submitted September 8, 1995)
- ATT 10.14b Nursing Care/Radiopharmaceuticals (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.15 Implant Therapy (Johnston-Willis Hospital Policy, July 24, 1990)
- ATT 10.15b Nursing Care/Implants (Johnston-Willis Hospital Policy, July 24, 1990)
- Att 11.1 Radioactive Waste (Johnston-Willis Hospital Policy, July 24, 1990)

All pertinent letters and other documents submitted for each facility should be included in the combined license. If there are any questions concerning this letter or the enclosed material, please contact Ms. Deletis at (804) 323-8796 or me at (804) 323-8801. Thank you for your assistance in this matter.

Sincerely,



Marilyn B. Tavenner
CEO

MBT/cl

Procedure for Calibrating Dose Calibrator

Procedure

1. Test for the following at the indicated frequency and for the suggested tolerance
 - a. Constancy at least once each day prior to assay of patient dosages (± 10 percent)
 - b. Linearity at installation and at least quarterly thereafter (± 10 percent)
 - c. Geometry dependence at installation (± 10 percent)
 - d. Accuracy at installation and at least annually thereafter (± 5 percent)
2. After repair, relocation or adjustment, repeat the above tests as appropriate.
3. **Constancy** means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Ba-133, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:
 - a. Assay the reference source(s) using a frequently used setting (i.e., Tc-99m may be the most frequently used setting).
 - b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
 - c. Weekly, using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Log the results.
 - d. The tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician and Radiation Safety Officer of suspected malfunction of the calibrator will be $\pm 10\%$. These action levels should be written in the log book.
 - f. If the value does not agree, within 5 percent, with the calibrator will be repaired or adjusted. If this is not possible, a calibration factor will be calculated for use during routine assays of radionuclides. If the value exceeds $\pm 10\%$, the dose calibrator must be repaired or replaced.
4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.
5. **Linearity** means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of activity which is at least as large as the highest dosage that will be administered to a patient, in a unit dosage syringe, or as a therapeutic radiopharmaceutical (whichever is largest).

Decay Method

- a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicurie. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Record the time of the assay. Continue on subsequent days until the assayed activity is less than 30 microcurie. For dose calibrators on which you select a range with a switch, select the range you would

- normally use for the measurement.
- c. Convert the time and date information you recorded to hours elapsed since the first assay
 - d. Plot or calculate the predicted activity versus the measured activity using a reading near a millicurie value frequently used for patient doses for a starting point.
 - e. If an error greater than $\pm 10\%$ is noted between the predicted and measured activities, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
6. **Geometry independence** means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.
- a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.
 - b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicurie indicated on the Dose Calibrator Geometry and Accuracy Form.
 - c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicurie indicated.
 - d. Repeat the process until you have assayed a 2.0-cc volume.
 - e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicurie by the millicurie indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."
 - f. If any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence", and note the date of the test and the model number and serial number of the calibrator.
 - g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicurie indicated.
 - h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicurie indicated.
 - i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
 - j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicurie by the millicurie indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."

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- k. If any correction factors are greater than 1.1 or less than 0.9 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence" and note the date of the test and the model number and serial number of the calibrator.
- 7 Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. The activity of at least one reference source should be within the range of activities normally assayed. At least two sources with different principal photon energies (such as Co-57, Ba-133, and Cs-137) should be used. The regulations require that, if a Ra-226 source is used, it must be at least 10 microcurie, if any other source is used, it must be at least 50 microcurie.
- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
 - b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.
 - c. Repeat the procedure for other calibrated reference sources.
 - d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the calibrator will be repaired or adjusted. If this is not possible, a calibration factor will be calculated for use during routine assays of radionuclides. If the average value exceeds $\pm 10\%$, the dose calibrator must be repaired or replaced.
 - e. At the time of the test the source used for daily constancy will be assayed on all commonly used setting and the results recorded
- 8 The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

Ministerial Change (§35 21) to incorporate the new Part 35 requiring allowing linearity tests to be carried down only to 30 uCi and to require the upper limit to only equal the largest dose administered.

Approved by RSC on: _____ Effective Date: _____

Radiation Safety Officer: [Signature] Date: _____

Chairman RSC: [Signature] Date: _____

Management Representative: [Signature] Date: _____

Personnel External Exposure Monitoring Program

Program

1. The Radiation Safety Officer will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low
2. Individuals who are occupationally exposed to radiation on a regular basis and who are likely to receive in excess of 10% of the annual occupational limit will be issued a whole body monitor that will be processed by a contract service on either a monthly or a quarterly basis. The determination for monitoring will be made by the Radiation Safety Officer.
3. Individuals who handle radioactive material on a regular basis and who are likely to receive in excess of 10% of the annual occupational limit to the extremities will be issued a film or TLD finger monitor that will be processed by a contract service on either a monthly or a quarterly basis.
4. All technologist working in radiology or nuclear medicine will be considered radiation workers and likely to receive in excess of 10% of the annual occupational limits and are therefore required to be monitored in accordance with items 2. and 3. above.
5. Individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for patients, will be issued a whole body monitor when caring for those patients, if the exposure is likely to exceed 10% of the individual's annual occupational limit.
6. Other individuals who are exposed to radiation on an occasional basis such as secretarial personnel who work in the vicinity of nuclear medicine but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages, will not normally be issued exposure monitors.
7. Any individual receiving occupational radiation exposure as a result of employment by any other person during the current calendar year must advise the RSO in writing of that exposure and provide in writing a quarterly summary of their exposure. Annually, they must also provide a copy of the NRC 5 form from each person providing personnel monitoring.

* All quarterly monitors will be of the TLD type

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Ministerial Change (§35.21) to incorporate the new Part 20 requiring for the reporting of exposure from other employers. Ownes is place on employee

Approved by RSC on: 3/1/95

Effective Date: 3/1/95

Radiation Safety Officer: [Signature]

Date: 3/10/95

Chairman RSC: [Signature]

Date: 3/1/95

Management Representative: [Signature]

Date: 4

RADIATION SAFETY COMMITTEE

Charge. The Committee is charged with identifying radiation safety problems, initiating, recommending, or provide corrective actions; and verifying the implementation of corrective actions. The Radiation Safety Committee is hereby delegated the authority to meet this charge.

The committee shall:

1. Review recommendations on ways to maintain individual and collective doses as low as reasonably achievable (ALARA);
2. Review, on the basis of safety and with regard to the training and experience standards in Subpart J of 10CFR35, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal; or
Review, pursuant to § 35.13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying and individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist
3. Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Sec. 35.31 of 10CFR35;
4. Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with radioactive material or a radiation producing device;
5. Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material or a radiation producing devices with respect to cause and subsequent actions taken; and
6. Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program to ensure compliance with the NRC regulations, the institutions license(s) and the goals of the ALARA Program.

Administrative Information

1. Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer. Other members may be included as the licensee deems appropriate.
2. The Committee must meet at least quarterly.
3. To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.
4. The minutes of each Radiation Safety Committee meeting must include:
 - (i) The date of the meeting;
 - (ii) Members present;
 - (iii) Members absent;
 - (iv) Summary of deliberations and discussions;
 - (v) Recommended actions and the numerical results of all ballots, and
 - (vi) ALARA program reviews described in § 35.20 (c).
5. The committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

Ministerial Change (§35.21) to incorporate the new Part 35 requiring allowing RSC to approve certain authorized users and nuclear pharmacist (FR Vol. 59, No231).

Approved by RSC on: 7/10/95

Effective Date: 7/10/95 2300081

Radiation Safety Officer: [Signature]

Date: 7/10/95

Chairman RSC: [Signature]

Date: 7/19/95

Management Representative: [Signature]

Date: 7/19/95

Program for Maintaining Radiation Exposure to Occupational Workers and Member of the General Public As Low As Reasonably Achievable (ALARA)

1. Management Commitment

- a. We, the management of this facility are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord 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 the 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 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 exposure ALARA.
 - (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 procedures and that individual 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 does overrule the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- c. Review of ALARA Program
 - (1) The RSC will encourage all users to review current procedures and develop new procedures 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 exposure 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 RSC, authorized users, and workers as well as those of management.

Table 1

Investigational Levels (mrem per calendar quarter)		
Area of Body	Level I	Level II
Total effective dose equivalent, general	125	375
Total effective dose equivalent, for physicians involved in angiography or cardiology	125	900
Shallow-dose equivalent, to skin or to any extremity	1,250	3,750
Eye dose equivalent	375	1,125
Deep-dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye	1,250	3,750

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 surveys.** 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.
- (4) **Annual review of doses to members of the general public.** The RSO will review the releases of both gaseous and liquid radioactive materials to determine that doses to members of the general public are ALARA in accordance with the provisions of Section 7 of this program and will report to the RSC.

b Education Responsibilities for ALARA Program

- (1) The RSO will schedule briefings and educational sessions to inform worker's and or their 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 causes. 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 exposures 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 exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5 Individuals Who Receive Occupational Radiation Exposure

- a Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
- b Workers 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 § 20.2106 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.

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- 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 reviews 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 others 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 causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions 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 Reestablishment 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.

- 7 This institution hereby establishes investigational levels for radiation dose to members of the general from releases of gaseous or liquid radioactive materials which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are 10% of the values listed in Appendix B, Table 2, Columns 1 and 2, to §§ 20.1001-20.2401. These levels apply to all members of the general public who may be exposed as a result of the release of radioactive materials from this facility.

8 Signature of Certifying Official

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

Marilyn Paenner
Signature

Marilyn Paenner
Name (print or type)

CEO
Title

9-8-95
Date

CHIPPENHAM MEDICAL CENTER
JOHNSTON WILLIS HOSPITAL

QUALITY MANAGEMENT PROGRAM - RADIONUCLIDE THERAPY

Purpose:

The following program has been established to ensure that the radionuclide therapy procedures carried out at these facilities 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 administration, a written directive must be prepared, dated, and signed by an authorized user for:

- Any brachytherapy radiation dose,
- Any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131; or
- Any therapeutic administration of a radiopharmaceutical, other than sodium iodine I-125 or I-131.

Definitions:

Misadministration means the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodine I-125 or I-131:
 - Involving the wrong patient or wrong pharmaceutical, or
 - When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceed 30 microcuries.
2. A therapeutic radiopharmaceutical dosage, other than sodium iodine I-125 or I-131:
 - Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or
 - When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
3. A brachytherapy radiation dose:
 - Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the body but that migrated outside the treatment site);
 - Involving a sealed source that is leaking;
 - When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.
4. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodine I-125 or I-131, both.

- Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and;
- When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

1. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

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

1. For any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131: the dosage;
2. For a therapeutic administration of a radiopharmaceutical other than sodium iodine I-125 or I-131: the pharmaceutical, dosage, and route of administration;
3. For all other brachytherapy:
 - Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - 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].

Recordable event means the administration of:

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;
2. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record.
3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodine I-125 or I-131 where both:
 - The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and
 - The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;
4. The therapeutic radiopharmaceutical dosage, other than sodium iodine I-125 or I-131, where the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

5. The brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Procedures:

1. Prior to administration, a written directive must be prepared, dated, and signed by an authorized user for:
 - Any brachytherapy radiation dose,
 - Any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131; or
 - Any therapeutic administration of a radiopharmaceutical, other than sodium iodine I-125 or I-131.

If, because of 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 revised written directive is signed by the authorized user within 48 hours of the oral revision.

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

If, because of the emergent nature of the patient's 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 immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

2. Prior to each administration, 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 ID card, the name on the patient's medical insurance card, or a photograph taken of the patient's face for ID purposes.
3. The final plans of treatment and related calculations for brachytherapy 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.

Computer-generated dose calculations will be checked by examining the computer printout to verify that the correct data for the patient were used in the calculation including the position applicator or sealed sources, the number of sources, total source strength, or source loading sequence.

4. Prior to each administration, it shall be verified that the administration is in accordance with the written directive.

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In the case of radiopharmaceutical, the radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical. The dosage should be measured in the dose calibrator and the result compared with the prescribed dosage in the written directive.

In the case of brachytherapy dose, the authorized user or qualified person under the supervision of the authorized user shall verify that the radioisotope, number of sources, source strength(s) to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources.

For temporary brachytherapy implants, radiographs or other comparable images of fixed geometry applicators, brachytherapy radioactive sources or nonradioactive "dummy" sources in place shall serve as the basis for verifying the position of the sources and calculating the exposure time or total dose. Except in the case of fixed geometry applicator, non-radioactive "dummy" sources will be used, whenever possible, before inserting the radioactive sources.

5. All unintended deviations from a written directive must be identified and evaluated, and appropriate actions taken, (see misadministration and recordable events).
6. 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.
7. Immediately after administration, the authorized user or a qualified person under the supervision of the authorized user, shall:
 - In the case of radiopharmaceuticals, make, date, and sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.
 - In the case of brachytherapy, the authorized user or qualified person under the supervision of the authorized user, make, date, and sign or initial a written record that documents the radionuclide, treatment site, total source strength, and exposure time (or, equivalently, the total dose) in the patient's chart or other appropriate record.
8. An annual review of the Quality Management Program will be performed by the Radiation Safety Officer (RSO) or his designee. The RSO 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 should include an evaluation of:
 - A representative sample of patient administrations based on 10% table of lot tolerance percent defects in 10 CFR 32.110 (b)(8).
 - All recordable events, and
 - All misadministrations to verify compliance with all aspects of the Quality Management Program.
 - For each case reviewed, the reviewer(s) should determine whether the administered radionuclide dosage was in accordance with the written directive.
 - If during the review, any previously unidentified misadministrations or recordable events are discovered, the representative sample of patients will be expanded to the 5% level. If an additional unidentified misadministrations or recordable events are discovered, all cases shall be reviewed.

A representative sample of patient administrations based on the table of lot tolerance percent defects in 10 CFR 32.110 (b)(8),

Number of Written Directives	Sample Size	
	10%	5%
1 to 25	All	All
26 to 50	17	30
51 to 100	20	37
101 to 200	22	40
201 to 800	23	45

A record of each review, including the evaluations and findings of the review, will be reported to be the Radiation Safety Committee and will be kept in an auditable 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.

If modifications are made to the program, a copy of the modified program must be submitted to the regional NRC office within 30 days.

9. **Recordable events**, within 30 days after the discovery of a recordable event, the Radiation Safety Officer shall:
 - Assemble the relevant facts including the causes;
 - Identify what, if any, corrective action is required to prevent recurrence; and
 - Make an auditable record of the relevant facts and what corrective action, if any, was taken.
10. **Misadministration**, the Radiation Safety Officer or his designee will immediately follow the steps outlined in 10 CFR 35.33 and make all appropriate reports and notification as well as advising administration of the incident.
11. **Record Retention**, each written directive, a record of each administered radiation dose and a record of each administered radiopharmaceutical dosage shall be retained for three years after the date of administration.
12. **Acceptance Testing**, will be performed before the first use of treatment planning or dose calculating computer program for brachytherapy dose calculations.

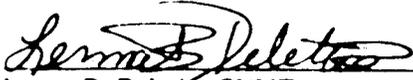
Quality Management Program

January 10, 1998

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Effective Date of Implementation:

June 29, 1993 (CMC) October 5, 1994 JWH; Combined and Revised January 10, 1996.

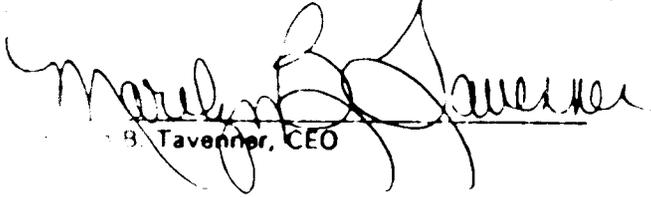


Lenna B. Deletis, CNMT

Radiation Safety Officer

Chippenham Medical Center/Johnston-Willis Hospital

1/15/96
Date



B. Tavenner, CEO

1/17/96
Date

Procedure for Safely Opening Packages Containing Radioactive Material

Procedure

1. The following procedure will be used for all radioactive packages received displaying a Radioactive White I, Yellow II or Yellow III label which are less than Type A quantities (see listing below):
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect the package for any sign of damage (e.g.; wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
 - c. wipe the external surface of the package (not required for gases). If there is any significant contamination, stop and immediately notify the Radiation Safety Officer.
 - d. Open the package with the following precautionary steps:
 - (1) Remove the packing slip.
 - (2) Open the outer package following the supplier's instructions, if provided.
 - (3) Open the inner package and verify that the contents agree with the packing slip.
 - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - (5) If anything is other than expected, stop and notify the RSO.
 - e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe to determine if there is any removable radioactivity by using the GM survey meter. If contamination is found:
 - (1) Notify the RSO.
 - (2) Take precautions against potential spread of contamination.
 - f. Check the user request to ensure that the material received is the material that was ordered.
 - g. Monitor the packing material and the empty packages for contamination before discarding.
 - (1) If contaminated, treat this material as radioactive waste.
 - (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
 - (3) If contaminated, go back to e of this section.
 - h. Make a record of the receipt.
2. The following procedure will be used for all radioactive packages received displaying a Radioactive White I, Yellow II or Yellow III label which are equal to or greater than Type A quantities (see listing below):
 - a. Follow all of the steps delineated in 1. with the additional requirement added to step c. Monitor the exposure levels at 3' from the package and at the surface of the package. If the exposure rate exceeds 10 mR/hr at 3 feet, or 200 mR/hr at the surface, or there is significant contamination, immediately notify the Radiation Safety Officer.

Listing of Type A Quantities
 (if nuclide is not listed refer to 10 CFR 71.4)

Nuclide	Activity in Curies
133 Ba	10
57 Co	90
60 Co	7
51 Cr	600
137 Cs	10
59 Fe	10
67 Ga	100
153 Gd	100
123 I	50
125 I	70
129 I	2
131 I	10
111 In	25
113m In	60
190 Ir	10
192 Ir	10
99 Mo	20
32 P	30
226 Ra	0.05
186 Re	20
188 Re	10
222 Rn	2
97 Ru	80
103 Ru	25
105 Ru	20
106 Ru	7
153 Sm	20
8 Sr	10
90 Sr	0.4
99m Tc	100
201 Tl	100
133 Xe	1000

Ministerial Change (§35.21) to incorporate the new Part 20 requiring for the reporting of exposure from other employers. Ownes is place on employee.

Approved by RSC on: 12-17-93

Effective Date: 12/15/93

Radion Safety Officer: [Signature]

Date: 12/15/93

Chairman RSC: [Signature]

Date: 12/15/93

Managment Representative: [Signature]

Date: 9