DMB COPY

September 19, 1985

48-24379-01

D. G. Wiedeman, Chief
Nuclear Materials Safety Section 1
Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, IL 60137

30-18556

Dear Mr. Wiedeman:

Enclosed is non-compliance report from your office dated July 16, 1985.

Attached is a memo from Roger C. Johnson, stating compliance action taken by Stan A. Huber Consultants.

I hope you find everything in order and I appologize for the delay in this matter.

Sincerely,

Steven H. Spencer
Executive Director

SHS/me
Enc.

IE07
1/1

SEP 23 1985

wmh
waupun memorial hospital • 620 west brown street
waupun, wisconsin 53963 • area code 414 324-5581

memo

DATE: 9-19-85

TO: Mr. Steve Spencer - Adm.

FROM: Roger C. Johnson, Dir. Radiology

SUBJECT: NRC Noncompliance report & report of compliance.

Steve-

Attached material must be sent to NRC today. Please find copy of non-compliances from D.G. Wiedeman and corrective action taken by Stan Huber consultants. The only area I had any direct personal control over is the write-up concerning the lack of Safety Comm. meetings. I wish to confirm to you at this time that the Safety Committee met 7-2-85. Members were polled for subject matter and need of meeting. Members declined. Next meeting set for 8-30-85. Minutes to that meeting [notes] attached. The confirmation of leak test being performed on our Cesium-137 dose calibrator reference standard is indicated on page four of SAHCI response dated 20 Aug. 1985. The last item is documentation from SAHCI indicating the removal of our Cobalt-57 source. At the time of removal, they also notified NRC and took care of related paperwork.

Thank you,

Roger Johnson, RT (ARRT)

Mgr., Dept. Medical Imaging

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

Copy to Rogn & Dorn

JUL 16 1985

Waupun Memorial Hospital
ATTN: Mr. Steven H. Spencer
Executive Director
620 W. Brown Street
Waupun, WI 53963

License No. 48-24379-01

Gentlemen:

This refers to the routine safety inspection conducted by Mr. D. R. Gibbons of this office on June 24-25, 1985, of activities at Waupun Memorial Hospital authorized by NRC Byproduct Material License No. 48-24379-01 and to the discussion of our findings with you and selected members of your staff at the conclusion of the inspection.

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

During this inspection, certain of your activities appeared to be in non-compliance with NRC requirements, as specified in the enclosed Appendix. A written response is required.

The responses directed by this letter (and the accompanying Notice) are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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

Sincerely,

D. G. Wiedeman

D. G. Wiedeman, Chief
Nuclear Materials Safety Section 1

Enclosure: Appendix,
Notice of Violation

cc w/enclosure:
DMB/Document Control Desk (RIDS)

~~8508020018~~

Appendix

NOTICE OF VIOLATION

Waupun Memorial Hospital License No. 48-24379-01

As a result of the inspection conducted on June 24-25, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

1. License Condition No. 16 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated August 23, 1984, states in Item 7 that the radiation safety committee will follow the duties and procedures as outlined in Appendix B of Regulatory Guide 10.8 dated October 1980. Appendix B requires that the radiation safety committee meet at least once each quarter.

   Contrary to this requirement, the radiation safety committee failed to meet at the required intervals. Specifically, the committee has had no recorded meeting since the license was issued, January 25, 1985, to the day of the inspection, June 24, 1985.

   This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 35.14(e)(1)(i) requires that sealed calibration or reference sources possessed pursuant to 10 CFR 35.14(d) be tested for leakage and/or contamination at intervals not to exceed six months.

   Contrary to this requirement, as of the day of the inspection, June 24, 1985, you have failed to leak test your '210' microcurie sealed cesium-137 reference source which you received on August 8, 1984, an interval of more than six months.

   This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

JUL 16 1985
Dated

D. G. Wiedeman, Chief
Materials Radiation Protection
Section 1

~~8508020079~~

sahci Consultants to Nuclear Medicine • Radiology • Nuclear Industry

STAN A. HUBER CONSULTANTS, INC. ☐ 200 NORTH CEDAR ROAD ☐ NEW LENOX, IL 60451 ☐ (815) 485-6161

August 20, 1985

Steven Spencer
Administrator
Waupun Memorial Hospital
620 West Brown Street
Waupun, Wisconsin 53963

Dear Mr. Spencer:

This is the summary report of my visit to your nuclear medicine facilities on July 22, 1985.

RADIATION SAFETY COMMITTEE

We reviewed the minutes for the quarterly meetings of the Radiation Safety Committee with Mr. Johnson and noted the Committee had no recorded meetings since the license was issued on January 25, 1985 to the day of the inspection by Mr. D. R. Gibbons on June 24, 1985. This was an item of non-compliance during that inspection.

There is no regulation regarding a "quorum" meeting to be present. Therefore, even a meeting of two members of the Committee to only comment on review of the film badge exposure reports would suffice for documentation purposes during unusually busy or vacation months.

LICENSING

1. We reviewed the NRC license documents and applications with Roger and he informed us that a physician user will need to be added to your facilities' NRC radioactive materials license. Jonathan Reed, M.D. was previously listed as a physician user at a facility in Nebraska. He need only obtain his training an preceptor statements that were submitted to the Nebraska Department of Health so that he may be included on Waupun Hospital's radioactive materials license. Since Nebraska is an agreement state, the NRC will not recognize just referencing the previous hospital license number. Upon receipt of the training and preceptor statements we will include Dr. Reed on your radioactive materials license and also delete Dr. Bricker who is no longer at Waupun Memorial Hospital. An additional statement will be added to the license for clarification of performing the day-of-use constancy checks on the dose calibrator with the Cesium-137 source. The Cobalt-57 source currently used is not a requirement.

2. A correction in the spelling of Waupun from "Waupon" to "Waupun" was included in amendment No. 1 along with the change of address.

INSPECTIONS

1. Mr. D.R. Gibbons conducted an inspection of the activities at Waupun Memorial Hospital on June 24, 1985. Two items of non-compliance were noted during his inspection as follows:

   a) Failure of the Radiation Safety Committee to meet at the required quarterly intervals. This was mentioned in the "Radiation Safety Committee" section of this report and Roger confirmed that quarterly meetings will be held to correct this.

   b) Failure to leak test the sealed Cesium-137 reference source which was received on August 8, 1984. This source was leak tested by SAHCI and the leak test certificate is enclosed with Roger's copy of this report for correcting this non-compliance item.

RADIATION SAFETY AND RECORD SYSTEMS

1. We did not review the film badge records during this visit and made a note to review them during our next scheduled visit.

2. The daily radiation surveys of the technologists' hands and clothing, dose prep, and patient injection, along with the weekly area radiation surveys were reviewed and these records were found to be in good order.

3. I confirmed that the quarterly physical inventory of sealed sources and reference standards need not be maintained at Waupun Memorial Hospital since the only source present is the Cesium-137 dose calibrator reference standard. This source is used each day to check the dose calibrator on days when scans are performed and this will serve as an inventory of the source.

4. We reviewed the routine required radiopharmaceutical accountability records for the documentation of receipt, use, and disposal of radioactive material and made the following suggestions:

   a) Document that any residual material has been returned to the pharmacy simply by writting "returned" on the slip provided by NPI.

   b) If any separate documentation is needed such as documentation for disposing of dose prep pads, syringes, etc. this can be documented on a separate sheet of paper.

   c) Simply record the patient's name on the nuclear pharmacy slip to keep all of the records for the patient's name, the dose received, and date on one slip of paper.

   d) Regarding the surveys on the source container I recommended that Roger perform wipe tests on the final source containers using just one wipe for these containers. It is not required that each individual dose be wiped unless the original wipe was found to be contaminated, in that case a more detailed survey should be conducted.

5. Several radiopharmaceutical suppliers have started using SI units (The International System of Units) on product labels and inserts to express activity, dose and dose rate. This is being done to comply with recent requirements by the FDA and other regulatory agencies. Also note that the current units are generally shown in parenthesis following the SI units. This practice is likely to continue for the foreseeable future. The actual activity in a vial remains unchanged.

   Here are some conversion factors you may find helpful:

   1 Becquerel (Bq) = 1 disintegration/sec

   1 Millicurie (mCi) = 2.22E9 dis/min or 3.7E7 dis/sec

   Therefore, 3.7E7 Bq = 1 mCi. The multiplier is E6 or 1,000,000 (Mega) so 1 millicurie = 37 megabequerels (MBq)

   Microcurie amounts will be given in Kilobequerels (KBq). Other SI conversions are as follows:

   1 Rad = 0.01 Gray (Gy)
   1 Rem = 0.01 Sievert (Sv)
   1 Roentgen = 0.000258 Coulomb/Kilogram (C/kg)

6. During our next visit we will perform the required annual ALARA radiation safety audit. This audit is a self-inspection checklist of the Nuclear Medicine Department's record system and items dealing with radiation safety and regulatory compliance.

7. I provided Roger with a "Caution Radioactive Material" sticker which was posted on the radioactive waste can in the Hot Lab section of the Nuclear Medicine Department to ensure that this waste container is not accidentally emptied by Housekeeping.

8. A major portion of this visit was spent reviewing a large manual of sample forms and written procedures which our firm developed to assist clients in maintaining organized and efficient record systems for inspections by the various regulatory accreditation agencies. As mentioned in the "Radiation and Record Systems" section of this report, forms were provided for documentation of each of the categories listed and reviewed with Roger.

SOURCE TRANSFER

SHHCI obtained the Cobalt-57 sealed source which is no longer needed for performing daily checks on the dose calibrator. Under separate cover we will forward to Roger Johnson the required documentation regarding the transfer of that source from the Nuclear Medicine Department to Stan A. Huber Consultants.

INSTRUMENTATION

1. I demonstrated the operational checks which need to be performed on the department's g.m. survey instruments. These checks are required to ensure that the instrument is functioning properly between calibration intervals.

A source contained on the side of the Victoreen survey instrument is license exempt.

2. We reviewed the day-of-use constancy checks on the dose calibrator and noted that on several occasions the readings had strayed out of the ±5% variance limit. We reviewed the calibrator sheet provided by NPI to Roger and confirmed that it was accurate. I explained the sheet as the first reading being the lower 5% limit with the middle reading being the current activity of the standard and the third being the upper 5% limit. I recommend that Roger watch this instrument carefully to ensure that this condition does not occur frequently. In the event that this continues I recommend that the unit either be replaced or repaired.

3. We reviewed the quarterly required linearity tests on the dose calibrator and confirmed that these were within the required ±5% variance. The linearity was reviewed and a new form provided to Roger for simplifying calculations and procedures. I confirmed that 48-hours is the maximum that need be carried out when performing this test.

4. A geometrical variation test has also been performed on the dose calibrator and it was well within the ±2% limits.

5. I performed the annual certified calibrations of the dose calibrator and two g.m. survey instruments. The certificates were left in the department for review and labels were attached to each of this instruments.

LEAK TESTS

I performed the semi-annually required leak testing of the Cesium-137 dose calibrator reference standard. Attached to Roger's copy of this report is the assay certificate for the department records.

REGULATIONS

The following is a list of recently issued NRC notices:

1. The NRC can cite non-compliance with 10CFR 35.14(b)(6) for administering a "routine" (FDA authorized) radiopharmaceutical by a route of administration that is not specified in package inserts. In the pending rewrite of 10CFR 35, the NRC is planning to include exemptions for dacrocystograms, LeVeen shunt studies, and R.N. cystograms, as it did for Tc-99m aerosol studies, listed in 35.14(b)(7). It would be a good idea to review your list of nuclear medicine procedures for the route of administration used. If the route is not I.V., oral or aerosol, or otherwise specified in the package insert, then you should call Cassandra McDonald at the NRC in Washington, D.C. at 301-427-4052 to see if the procedure is scheduled to be included in the list of 35.14 (b)(7) exemptions. If not, she can tell you how to submit a written request to include the procedure in the list of exemptions. The NRC will only consider written requests. If an exemption is needed, this relatively simple request can avoid a potential NRC non-compliance citation and avoid the need to submit an IND (Investigational New Drug) application to the FDA.

2. On January 4, 1985 the NRC sent a notice to all NRC licensees to clarify its procedures for public disclosure of information contained in license applications. In fact, any documents submitted to the Nuclear Regulatory Commission will normally be made available for public inspection per Title 10 CFR Section 2.790. Exceptions include classified data, trade secrets, and personnel and medical files. The NRC recommends that you not include in any submittal trade secrets or personal information about your employees, unless the information is directly related to radiation safety or specifically required by NRC. Any of the aforementioned information that you wish to be withheld from public disclosure, if submitted to the NRC, requires a request for withholding in accordance with the procedure specified in 10 CFR Section 2.790. The NRC Regional Licensing Branch, as listed on the NRC "Notice to Employee" signs in all licensed facilities, may be contacted at any time, if questions arise about this topic.

3. A February 14, 1985 Federal Register notice indicates the NRC is calling a Medical Advisory meeting for May 3, 1985 to assist in deciding whether changes are needed for the training and experience criteria for physician users to be licensed for medical use of byproduct material. The main controversy centers about licensing for "all nuclear imaging procedures" versus "nuclear cardiology imaging only". It seems in both cases there are proposals for 700 hours of clinical experience, instead of the current 500 hours. This does not affect currently licensed nuclear physicians, but would affect the requirements for new physicians (not previously licensed for nuclear procedures) to be added to a license.

4. A February 28, 1985 Federal Register notice indicates the NRC denied a petition of Nuclear Radiation Consultants (Lunar Corp.) for general licensing"for any health professional" to use a Gd-153 dual photon spine scanner for bone mineral analysis. Proposed users of that device must generally still obtain a specific NRC license or amendment. The NRC agreed with 27 comment letters it received, which all opposed adoption of the petition, primarily for the reason that only physicians should be licensed for medical use of diagnostic devices. In essence, this ruling does not represent any change in current licensing procedures, but we are summarizing this notice due to the extensive interest in bone densitometry and osteoporosis.

5. A February 25, 1985 Federal Register notice allows all NRC Group II and III licensees to use Tc-99m sodium pertechnetate for nasolacrimal imaging (dacrocystograms) and sulfur colloid for esophageal imaging (esophageal transit, gastroesophageal reflux, and pulmonary aspiration of gastric contents in adults and children), even though these procedures are not yet listed in some manufacturer package inserts. The maximum recommended dosage is 100 microcuries for dacrocystograms. For gastroesophageal studies the suggested oral dose is 150 to 300 microcuries in adults, and for pulmonary aspiration studies, 300 to 500 microcuries. For children dosages, the suggested dosages for both these studies is 100 to 300 microcuries.

GENERAL

1. We briefly discussed the ND-1100A bone densitometer. This instrument is used for bone mineral analysis for diagnosis of early stage osteoporosis or osteoporotic tendency. Product literature was left with Roger during our visit.

2. We discussed SAHC!'s services with Roger and he informed me that a decision will be made as whether to keep us on the current semi-annual consulting visits or increase this to a quarterly visit.

Thank you for the opportunity of serving you. An exact date will be scheduled with you in advance.

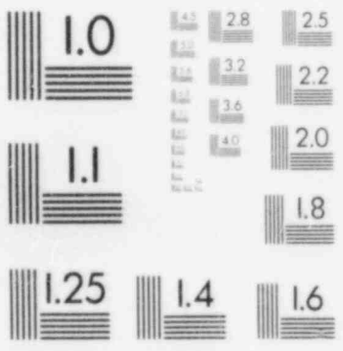
Sincerely,

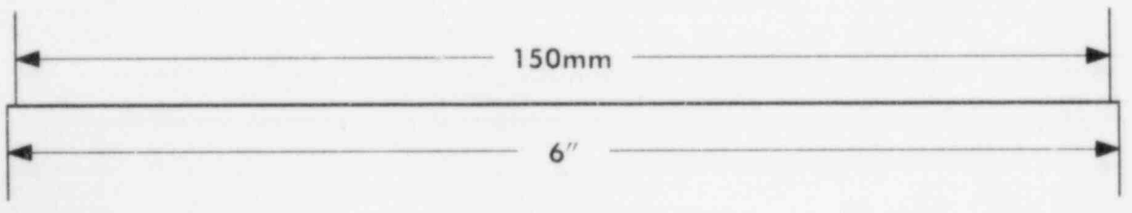
John J. Hollinden

John J. Hollinden
Nuclear Consultant

cc: Steven Rawlins, M.D., Radiology
Roger Johnson, Radiology Administrator

IMAGE EVALUATION
TEST TARGET (MT-3)





ISOTOPE SAFETY COMM. MEETING

Fri. 8-30-81 07:45

Notified - Tu, Rawlins, Boydston, Buchholz

Present - Tu, Rawlins, Boydston, Buchholz, Johnson

Agenda:

1. a) Purpose of meeting - To review policies & procedures, film badge reports, NRC inspections & results, JCAH standards, nuclear medicine consultant surveys & recommendations & cover general areas of concern or medical care problems relating to the radiation safety of hospital patients and employees.

b) Required to attend - Radiation safety officer, representative from adm, representative from internal medicine, director of nursing and director of Medical Imaging.

c) Frequency of meetings - quarterly required by NRC & JCAH.

2) Give film badge report - All technicians handling radiopharmaceuticals must wear & (explain reporting process)

3) Pass out P & P's

4) Letter from Spencer

5) Read report from Gibbons.

6) Read specific violations & elaborate on leak test.

7) Read letter from Stan Hubsa on next page corrections of the two non-compliances

8) Interesting case file available meetings, etc.

9) Recognize Pan with her concern

Roger C. Johnson

sahci Consultants to Nuclear Medicine • Radiology • Nuclear Industry

STAN A. HUBER CONSULTANTS, INC. ☐ 200 NORTH CEDAR ROAD ☐ NEW LENOX, IL 60451 ☐ (815) 485-6161

August 20, 1985

Roger C. Johnson, R.T.
Radiology - Nuclear Medicine Department
Waupun Memorial Hospital
620 W. Brown
Waupun, WI 53963

RE: Transfer of a Radioactive Standard

Dear Mr. Johnson:

This is to confirm that the required documentation was provided to you regarding the transfer from your Nuclear Medicine Department on July 22, 1985, of the following Cobalt-57 source:

Cobalt-57 sealed source from New England Nuclear (NEN) containing 4.8 mCi on September 5, 1984; Serial Number 2060984A-31.

A copy of the leak test performed prior to the transport of this source is enclosed, ensuring the source was not leaking while it was in your possession and at the time of transfer. Also enclosed is a copy of the original certificate of radioactivity calibration and leak test certificate.

This transfer relieves you from any further inventory or leak test requirements for this standard.

If you have any questions, please feel free to contact our office.

Sincerely,

John J. Hollinden
Nuclear Consultant

JJH:jms

Enclosure