



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

OCT 21 1993

Docket No. 030-19521
License No. 50-19913-01

Ketchikan General Hospital
3100 Tongass Ave
Ketchikan, Alaska 99901

Attention: Ed Mahn
Hospital Administrator

Thank you for your letter dated October 4, 1993, informing us of the steps that you have taken to correct the items which we brought to your attention in our letter dated September 14, 1993. Your corrective actions will be verified during our next inspection.

In your response to violation C of our Notice of Violation dated September 14, 1993, you enclosed a new written policy and procedure (Attachments II and III) that you plan to use for credentialing visiting authorized users in your licensed program. We have two comments regarding the Attachment II procedure. First, the words: "broad license" should be added to Item 2, line 4 after "Agreement State" to correspond with the requirement in 10 CFR 35.27(a)(2). Second, we note the absence of any procedure in Attachment II for reviewing the license or permit naming the prospective visiting authorized user to ensure that the named individual has been specifically authorized by that license or permit for the medical procedures to be performed under Ketchikan Hospital's NRC license, for compliance with 35.27(a)(3). You should consider revising the Attachment II procedure to address the above concerns. Any revision to the procedure that you plan to implement should be maintained on file for review during our next inspection.

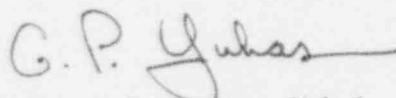
In addition, your letter did not include a response to our request for information describing the administrative controls that will be established to improve the management oversight of your overall licensed program to prevent violations of NRC requirements (see page 2, paragraph 3 of our September 14th letter). Please submit the requested information within 30 days of the date of this letter.

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PDR ADOCK 03019521
C PDR

Finally, in your response you requested that our inspectors evaluate whether Ketchikan Hospital will ever be able to meet all NRC requirements for which it is held accountable. We expect that all licensees will devote sufficient resources to meet all of the requirements imposed by NRC regulations and license conditions. If a licensee decides for any reason that it cannot comply with all NRC requirements then it should either obtain exemptions from those requirements pursuant to 10 CFR 30.11, or cease operations and initiate termination of its license.

If you have any questions or comments on this matter, please contact the undersigned at (510) 975-0226 or Mr. David D. Skov at (510) 975-0253.

Sincerely,

A handwritten signature in cursive script that reads "G.P. Yuhas". The signature is written in dark ink and is positioned above the typed name.

Gregory P. Yuhas, Chief
Radioactive Materials Safety Branch

bcc w/enclosure:
Docket File
Inspection File
G. Cook
R. Huey
B. Faulkenberry
State of Alaska

bcc w/o enclosure:
M. Smith
D. Clevenger

Region V/dds

DSkov ~~10/21/93~~
10/21/93
10/28/93

~~10/21/93~~
RHuey
10/25/93

GPJ
GYuhas
10/21/93

REQUEST COPY	REQUEST COPY	REQUEST COPY	REQUEST COPY	SEND TO PDR
YES / NO	YES / NO	YES / NO	YES / NO	YES / NO

080015

KETCHIKAN GENERAL HOSPITAL

3100 TONGASS AVE.
KETCHIKAN, ALASKA 99901-5794
907-225-5171
FAX # 907-225-2173

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NRC
REGISTRY

October 4, 1993

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

RE: Notice of Violation
Ketchikan General Hospital
Docket No. - 030-19521
License No. - 50-19913-01

This is the response to the Notice of Violation resulting from the inspection conducted by Mr. David D. Skov on August 17-19 and 24, 1993 at Ketchikan General Hospital, Ketchikan, Alaska.

- A. 10 CFR 35.50 (b)(3) and (b) (4) require, in part, that a licensee test each dose calibrator upon installation for linearity and for geometry dependence on the range of volume and volume configurations for which it will be used.
1. Reason for violation - The unit in question was on temporary loan from Health Physics Northwest. An assumption was made that calibration and testing done on the unit by Health Physics was adequate for the temporary use of the unit.
 2. Corrective steps taken - Not applicable as machine is no longer on site.
 3. Corrective steps to avoid future violations - A policy and procedures has been written for the Nuclear Medicine Department that addresses the need to have all dose calibrators, new, used and rental units, tested for linearity and geometry prior to use at the facility. (See Attachment I).
 4. Date of compliance - September 30, 1993
- B. 10 CFR 35.50 (e)(2),(3) and (4), 35.59(d) and 35.59 (g) require, in part, that a licensee retain records of dose calibrator annual accuracy tests, quarterly linearity tests, geometry dependence tests, sealed source leak tests, and sealed source inventories, respectively, and that the records include, in part, the signature of the Radiation Safety Officer.
1. Reason for violation - The lack of signature was an oversight when the review was done by the RSO.

KGH

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Part B (cont.)

2. Corrective steps taken - All signatures were put in place during the Radiation Safety Committee meeting of Sept. 8, 1993.
 3. Corrective steps to avoid future violations - The review with accompanying signatures will take place at each quarterly Radiation Safety Committee meeting so that more than one person can ensure that signatures are in place.
 4. Date of compliance - September 8, 1993.
- C. 10 CFR 35.27(a)(1) and (2) provides, in part, that a licensee may permit any visiting authorized user to use licensed material for medical use under the terms and condition of the licensee's license for sixty days each year if the licensee has the prior written permission of the institution's Radiation Safety Committee, and if the licensee has a copy of license issued by the Commission or an Agreement State or a permit issued by a Commission or Agreement State broad licensee that identifies the visiting authorized user by name as the authorized user for medical use.
1. Reason for violation - There was a breakdown in the credentialing process. Information was faxed, however, the copy was not legible and was discarded without followup.
 2. Corrective action taken - The issue was discussed at the Radiation Safety Committee on September 8, 1993. It was agreed to develop a more stringent credentialing process in order to ensure that all proper documentation is in place.
 3. Corrective steps to avoid future violations - A new policy and procedure was written for the purpose of credentialing locum tenens radiologists. The Diagnostic Radiology Privilege form was also revised to include a checklist to ensure that privileges are not granted without proper documentation of NRC licensure. (See Attachment II and Attachment III).
 4. Date of compliance - September 30, 1993.
- D. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Section D (cont.)

1. Reason for violation - The Nuclear Medicine Department has only one trained technologist. When this technologist is on vacation the nuclear medicine unit is closed and no procedures are performed. Weekly testing was not performed due to unavailability of trained personnel. The hospital was not aware that testing had to be completed even when the unit was closed.
2. Corrective action taken - See #3.
3. Corrective steps to avoid future violations - A technologist will be trained to conduct radiation detection testing for all applicable areas during the absence of the nuclear medicine technologist. This person will be trained only to perform the tests under the supervision of the Radiation Safety Officer.
4. Date of compliance - Training will begin November 1, 1993 and it is anticipated that it will be completed by May 30, 1994.

E- 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.

1. Reason for violation - The Nuclear Medicine Department has only one trained technologist. When this technologist is on vacation the nuclear medicine unit is closed and no procedures are performed. Radiopharmaceuticals are not prepared or administered. Weekly testing was not performed due to unavailability of trained personnel. The hospital was not aware that testing had to be completed even when the unit was closed.
2. Corrective action taken - See #3.
3. Corrective steps to avoid future violations - A technologist will be trained to conduct radiation detection testing for all applicable areas during the absence of the nuclear medicine technologist. This person will be trained only to perform the tests under the supervision of the Radiation Safety Officer.
4. Date of compliance - Training will begin November 1, 1993 and it is anticipated that it will be completed by May 30, 1994.

NRC Violation
Page 4.....

I hope that the violations have been addressed fully per the NRC requirements. I would like to thank you for noting the significant improvements we have made to comply with NRC regulations and requirements. We feel that we are making great strides toward full compliance due to the direct supervision of Terry Lesko, M.D. We are a small facility in a remote location. We provide nuclear medicine procedures as a service to our community without any anticipation of recoupment of resources. We are looking forward to the early reinspection of our licensed program that Mr. Gregory Yuhas referred to in his letter of September 14, 1993. With this in mind, we respectfully request that during the reinspection of our licensed program that your inspectors evaluate whether we, as a small institution, will ever be able to meet all the requirements for which we are held accountable. Since we operate this unit on a breakeven basis, further monetary violations, in spite of good intentions, could prove cost prohibitive in the future. Since the cost of healthcare is of national interest, we may all feel that we can better serve our patients in a more cost effective manner by not providing nuclear medicine procedures.

Thank you for your consideration to our request.

Sincerely,



Edward Mahn
Administrator

Attachments

cc: U.S. Regulatory Commission
Region V
1450 Maria Lane
Walnut Creek, CA 94596-5368

pa

KETCHIKAN GENERAL HOSPITAL
POLICY AND PROCEDURE MANUAL
NUCLEAR MEDICINE DEPARTMENT

POLICY: Dose calibrator "testing" procedure prior to
installation

APPROVAL: Radiation Safety Officer

EFFECTIVE DATE: 9/93

PROCEDURE:

Prior to any usage of any dose calibrator, whether it is new, used or rental unit, it must be tested for both linearity and geometry prior to its use in the Nuclear Medicine Department of Ketchikan General Hospital. This is in accordance with Nuclear Regulatory Commission Regulation 10 CFR 35, 50 (B) (3) and (B) (4).

The test results must be submitted to the Radiation Safety Officer for review and approval (signature required). Thereafter, any test results shall be presented to the next scheduled Radiation Safety Committee for final approval.

ATTACHMENT II

POLICY AND PROCEDURE MANUAL
ADMINISTRATION

POLICY: Credentialing for Radiology Locum Tenens
APPROVAL: Radiation Safety Officer _____
Administrator _____
EFFECTIVE DATE: 9/93

PROCEDURE:

1. The applicant will provide a completed application form, privilege form and all other documentation required by all locum tenens applicants.
2. In addition to the above, the applicant will provide a copy of a license issued by the Nuclear Regulatory Commission or an Agreement State or a permit issued by a Commission or an Agreement State that identifies the visiting authorized user by name as the authorized user for medical use.
3. When the applicant's file is complete with all proper documentation, a special meeting of the Radiation Safety Committee will be called to review the credentials of the applicant.
4. Upon approval of the Radiation Safety Committee, the Radiation Safety Officer (who is also the Chief of Service) will sign on the appropriate line.
5. Following approval by the Radiation Safety Committee, the credentialing file will be presented for approval to the Chief of Staff (Chairman of the Executive Credentials Committee) and the Administrator (Chairman of the Governing Board).

KETCHIKAN GENERAL HOSPITAL

Diagnostic Radiology Privileges

Privileges in Diagnostic Radiology shall be based on adequate documentation of training and experience and continuing demonstration of adequate technical skill and appropriate patient care as evaluated day to day by peers and as evaluated periodically by the Medical Review Committee. Initial each procedure for which you are seeking privileges to perform.

General Diagnostic Radiology

- _____ Plain film interpretation
- _____ Performance of and interpretation of films produced during UGI, BE, IVP, and other like general contrast exams.

Special Contrast Examinations

- _____ Arteriography head and neck
- _____ Arteriography visceral
- _____ Arteriography extremity
- _____ Arteriography aorta
- _____ Venography extremity
- _____ Venography inferior vena cava
- _____ Venography superior vena cava
- _____ Lymphangiography
- _____ Myelography lumbar and thoracic via lumbar puncture
- _____ Myelography cervical via C1-C2 puncture
- _____ Sialography
- _____ Hysterosalpingography
- _____ Cystourethrography
- _____ Renal cyst puncture and injection
- _____ Percutaneous antegrade pyelography
- _____ Percutaneous transhepatic cholangiography
- _____ Arthrography TMJ
- _____ Arthrography shoulder
- _____ Arthrography elbow
- _____ Arthrography wrist
- _____ Arthrography hip
- _____ Arthrography knee
- _____ Arthrography ankle
- _____ Arthrography vertebral facet joint
- _____ Bronchography
- _____ Cisternography
- _____ Dacryocystography
- _____ Diagnostic pneumoperitoneography
- _____ Other

Special Interventional Procedures

- _____ Percutaneous abscess drainage
- _____ Percutaneous biopsy head and neck
(extracranial)
- _____ Percutaneous biopsy thorax
- _____ Percutaneous biopsy abdomen
- _____ Percutaneous biopsy retroperitoneum
- _____ Percutaneous biopsy pelvis
- _____ Percutaneous biopsy extremity
- _____ Percutaneous biopsy spine and other osseous
structures
- _____ Percutaneous biliary drainage
- _____ Percutaneous nephrostomy
- _____ Percutaneous gastrostomy
- _____ Percutaneous thoracentesis, paracentesis,
amniocentesis
- _____ Introduction of intraluminal drainage tube
(e.g., Miller-Abbott tube)
- _____ Other

Ultrasonography

- _____ Neonatal head
- _____ Neck thyroid
- _____ Neck carotid and vertebral
- _____ Heart M-mode
- _____ Heart 2-D realtime
- _____ Heart Doppler (pulsed and continuous wave)
- _____ Chest wall and pleural space
- _____ Abdomen liver and pancreas
- _____ Abdomen kidneys
- _____ Abdomen great vessels
- _____ Pelvis
- _____ Gravid uterus and fetus
- _____ Testicles
- _____ Abdominal wall and soft tissue of the extremity
- _____ Other

Nuclear Medicine Imaging

- _____ Brain
- _____ Cerebrospinal fluid spaces
- _____ Thyroid and parathyroid
- _____ Vascular flow
- _____ Lung perfusion
- _____ Lung ventilation
- _____ Heart myocardial
- _____ Heart wall-motion
- _____ Liver-spleen reticuloendothelial system
- _____ Liver biliary scintigraphy
- _____ Renal cortical
- _____ Renal GFR functioning
- _____ Isotopic cystography for v-u reflux detection
- _____ Bone scintigraphy
- _____ Marrow scintigraphy

- _____ Skeletal muscle (thallium 201)
- _____ Adrenal
- _____ Abscess and/or tumor scintigraphy
- _____ Thrombosis scintigraphy
- _____ Other

Computerized Tomography

- _____ Head brain
- _____ Head petrous pyramids
- _____ Head orbits, face, paranasal sinuses
- _____ Thorax
- _____ Abdomen and retroperitoneum
- _____ Pelvis
- _____ Spine
- _____ Extremity
- _____ Neck soft tissues
- _____ Other

_____ Documentation of NRC Licensure (Please attach to this form)

Applicant's Signature Date

Chief of Service Signature Date
(Radiation Safety Officer)

Chairman, Exec-Credentials Committee Date

Chairman, Governing Board Date