U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 12

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301881

Licensee	
1. Principal Knox Co. d/b/a Starke Memorial Hospital 2. 102 East Culver Road Knox, IN 46532	In accordance with letter dated October 3, 1995, 3. License Number 13-15399-01 is amended in its entirety to read as follows: 4. Expiration Date May 31, 2004 5. Docket or Reference No. 030-09044

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (not to exceed 1 curie of I-131)
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. In vitro studies.

0/1

2-30-96

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 13-15399-01

Docket or Reference Number 030-09044

Amendment No. 12

CONDITIONS

10. Location of Use: 102 East Culver Road, Knox, Indiana.

11. Radiation Safety Officer: Richard A. Boyd, M.D.

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
Richard A. Boyd, M.D.	35.100, 35.200, 35.300 and 31.11
Surjit S. Patheja, M.D.	35.100, 35.200, 35.300 and 31.11
E. Tufekcioglu, M.D.	35.100, 35.200, 35.300 and 31.11
U. B. Blando, M.D.	35.100, 35.200, 35.300 and 31.11
Anil Kothari, M.D.	35.100, 35.200, 35.300 (excluding thyroid carcinoma) and 31.11
James M. Forde, M.D.	35.100, 35.200, 35.300 and 31.11
William R. Kelly, M.D.	35.100, 35.200, 35.300 and 31.11
Mary Newell, M.D.	35.100, 35.200 and 31.11
Usha Sharma, M.D.	35.100, 35.200 and 31.11

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 13-15399-01

Docket or Reference Number 030-09044

Amendment No. 12

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated February 10, 1994 (excluding any reference made to QMP); and

B. Letters dated October 3, 1995, and October 17, 1995 and September 26, 1996 (with Attachment 1).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/15/96

By Michael F. Weber
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20040531
Fee Comments: CODE 13
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: PRINCIPAL KNOX COMPANY
   Received Date: 960926
   Docket No: 3009044
   Control No.: 301881
   License No.: 13-15399-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 0
   Check No.: 0

3. COMMENTS

Signed D. Hersey
Date 9-25-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: 7C $440

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 10/15/96

OCT 23 1996

Log OCT 1 III
Remitter
Check No. 71518
Amount $440
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 10/15/96
Date Completed 10/15/96
By SC

1996 OCT -3 AM 11:09

WALLER LANSDEN DORTCH & DAVIS
A PROFESSIONAL LIMITED LIABILITY COMPANY
NASHVILLE CITY CENTER
511 UNION STREET, SUITE 2100
POST OFFICE BOX 198966
NASHVILLE, TENNESSEE 37219-8966
(615) 244-6380

FACSIMILES
(615) 244-6804
(615) 244-5686

809 SOUTH MAIN STREET
P. O. BOX 1035
COLUMBIA, TN 38402-1035
(615) 388-6031

September 26, 1996

Via Federal Express

Mr. John Madera
Chief - Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
801 Warrensville Road
Lisle, Illinois 60523-4351

Re: Leasing of Starke Memorial Hospital

Dear Mr. Madera:

As we discussed this morning, I have enclosed for your review the following:

1. One original response to Form 89-25 and attachments;

2. One copy of my letter to you of September 19, 1996 notifying you of the transaction.

As I have previously indicated to you, there will be no change in the following: personnel having immediate control over licensed activities, radiation safety officer, authorized user(s), organization, location, facilities, equipment, procedures or personnel.

Thank you for your cooperation and assistance in this matter. If you have any questions or comments, or feel you need further information in order to make a determination of consent, please do not hesitate to call me immediately. My direct line is 615/252-2406.

Very truly yours,

Kellie A. Little
Paralegal

/kl
Encl.
cc: Mr. Martin Rash
Howard T. Wall, Esq.
Kevin D. Norwood, Esq.
Nora L. Liggett, Esq.
Michelle B. Marsh, Esq.

PM: 9-26-96

INFORMATION NEEDED FOR CHANGE OF OWNERSHIP APPLICATION

The-applicant should provide the following information concerning changes of ownership or control by the applicant (transferor and/or transferee, as appropriate):

The Applicant, Principal Knox Company, a Delaware corporation (the "Transferee") provides the following information to the Nuclear Regulatory ("NRC"), concerning its leaseholdership of Starke Memorial Hospital (the "Transferor").

1. The new name of the licensed organization. If there is no change, the licensee should so state.

   The name of the licensed organization will be Principal Knox Company d/b/a Starke Memorial Hospital.

2. The new licensee contact and telephone number(s) to facilitate communications.

   The new licensee contacts and telephone number to facilitate communications is: 5123 Paddock Village Court, A-12, Brentwood, Tennessee 37037.

3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.

   As currently proposed, Transferor will be leased by Transferee. A list of Transferee's officers and directors is attached. The day-to-day operations of the Transferor will be managed by Transferee.

   There will be no changes in Transferor's staff, radiation safety officer, authorized users, or any other person identified in the current license.

4. An indication of whether the transferor will remain in non-licensed business without the license.

Transferor, Starke Memorial Hospital, a County Hospital organized pursuant to the State of Indiana Acts of 1917, Chapter 144, will not remain in non-licensed business without the license.

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name chances and changes of ownership.

As set forth above, the Transferor will be leased by the Transferee, which will manage the Transferor's day-to-day operations.

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).

There are no planned changes in organization, location, facility, equipment, or procedures.

7. A detailed description of any changes in the use, possession, location or storage of t licensed materials.

There will be no change in the use, possession, location or storage of the licensed materia

8. Any changes in organization, location, facilities, equipment, procedures, or personnel th would require a license amendment even without the change of ownership.

There will be no change in organization, location, facilities, equipment, procedures, personnel that would require a license amendment even without the change of ownershi

9. An indication of whether all surveillance items and records (e.g., calibrations, leak tes surveys; inventories, and accountability requirements) will be current at the time of transf A description of the status of all surveillance requirements and records should also provided.

All surveillance items and records will be current at the time of transfer. A description the status of all surveillance requirements and records is attached as Exhibit C. [Plea attach description or most recent survey.

10. Confirmation that all records concerning the safe and effective decommissioning of t facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; a waste disposal by release to sewers, incineration, radioactive material spills, and on-s burials, have been transferred to the new licensee, if licensed activities will continue at t same location, or to the NRC for license terminations.

All records concerning the safe and effective decommissioning of the facility, pursuant 10 CFR 30.35(g), 40.36(f), 70.25(g) and 72.30(d); public dose; and waste disposal l release to sewers, incineration, radioactive material spills, and on-site burials, will l transferred to the new licensee at the time of the closing of the transaction, current anticipated to occur on or about September 30, 1996.

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

There is no contamination of facilities and/or equipment.

12. A description of any decontamination plans, including financial assurance arrangement of the transferee, as specified in 10 CFR 30.35, 40.36, and 70.25. This should includ information about how the transferee and transferor propose to divide the transferor' assets, and responsibility for any cleanup needed at the time of transfer.

There is no contamination of facilities and/or equipment.

13. Confirmation that the transferee agrees to abide by all commitments and representation previously made to NRC by the transferor. These include, but are not limited to maintaining decommissioning records required by 10 CFR 30.35(g); implementin decontamination activities and decommissioning of the site; and completing correctiv actions for open inspection items and enforcement actions.

Transferee agrees to abide by all commitments and representations previously made t NRC by the Transferor.

With regard to contamination of facilities and equipment, the transferee should confirm in writing, that it accepts full liability for the site, and should provide evidence of adequat resources to fund decommissioning; or the transferor should provide a commitment t decontaminate the facility before change of control or ownership.

There is no contamination of facilities and/or equipment.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

There are no open inspection items.

14. Documentation that the transferor and, transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

As set forth above, there are no inspection items.

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

Transferee agrees to abide by all commitments and representations previously made to NRC by the Transferor.

Dated as of this 25 day of September, 1996.

TRANSFEROR:

STARKE MEMORIAL HOSPITAL

By: Kathryn J. Norem

Title: Administrator

TRANSFEREE:

PRINCIPAL HOSPITAL COMPANY

By: Martin S. Rash

Title: President

minutes from last meeting 7/18/96 to follow

RADIATION SAFETY COMMITTEE MINUTES

STARKE MEMORIAL HOSPITAL

DATE: TUESDAY, MARCH 5, 1996

PLACE: CONFERENCE ROOM

PRESENT: DR. BOYD, RADIATION SAFETY OFFICER; MRS. KATHY NOREM, R.N., CHIEF EXECUTIVE OFFICER OF STARKE MEMORIAL HOSPITAL AND LORI CAPUTO, CHIEF OF DIAGNOSTIC SERVICES.

ABSENT: NONE

PREVIOUS MINUTES: MINUTES OF THE PREVIOUS MEETING WERE NOT AVAILABLE AND WILL BE REVIEWED AT THE NEXT RADIATION SAFETY COMMITTEE MEETING.

NEW BUSINESS:

BADGE REPORTS ON ALL EMPLOYEES INDICATE READINGS BELOW 10% OF MAXIMUM PERMISSIBLE DOSE AS RECOMMENDED IN THE ALARA PROGRAM.

IT WAS ANNOUNCED THAT THE NUCLEAR REGULATORY COMMISSION HELD AN INSPECTION OF THE NUCLEAR MEDICINE PROGRAM AT STARKE MEMORIAL HOSPITAL ON 1-26-96. A POST INSPECTION TELEPHONE CONFERENCE WAS HELD BETWEEN THE INSPECTOR, MR. ROBERT G. GATTONE AND DR. BOYD. THIS CONVERSATION WAS HELD ON 2-13-96. WHILE THERE WERE NO VIOLATIONS OF THE N.R.C. REQUIREMENTS ON THE INSPECTION, THERE WERE A FEW ITEMS OF CONCERN PRESENTED TO DR. BOYD. THE NUMBER ONE CONCERN WAS INVOLVING THE USE OF DOSE RANGES ON WRITTEN DIRECTIVES. IT IS NOTED THAT DOSE RANGES ARE NOT ACCEPTABLE ON WRITTEN DIRECTIVES AND THE DOSE ORDERED MUST BE A SINGLE VALUE. IF THERE NEEDS TO BE AN AMENDMENT TO THE WRITTEN DIRECTIVE, THIS CAN PERFORMED PRIOR TO ADMINISTERING THE RADIONUCLIDE TO A PATIENT. IT WAS ALSO INDICATED THAT THE EXPECTED ACTIVITY OF THE DOSE CALIBRATION FORMS NEEDS TO BE UPDATED AND THAT THE CONSTANCY CHECK FORMS NEED TO BE UPDATED. ALSO, A CONCERN WAS THAT RADIATION SAFETY MINUTES INCLUDE THOSE MEMBERS PRESENT AND ABSENT AS WELL AS AN ALARA REVIEW. A FINAL ITEM OF CONCERN WAS REGARDING THE CESIUM 200 MILLICURIE SOURCE, WHICH IS BEING STORED IN A CONTAINER OTHER THAN THE ORIGINAL GREEN VIAL THAT THE SOURCE CAME IN. THE GREEN VIAL IS TORN AND SHOULD NOT BE USED TO STORE THE CESIUM SOURCE. NONE OF THE CONCERNS VOICED BY MR. GATTONE REQUIRE A WRITTEN RESPONSE TO THE N.R.C.

IT WAS INDICATED TO THE COMMITTEE THAT THE NUCLEAR MEDICINE TECHNOLOGIST HAD RESIGNED FROM STARKE MEMORIAL HOSPITAL ON APPROXIMATELY JANUARY 16, 1996 LEAVING NO NUCLEAR TECHNOLOGIST IN THE HOSPITAL. AS A RESULT OF THE TECHNOLOGIST LEAVING THE HOSPITAL, THE NUCLEAR PROGRAM HAS BEEN INACTIVE SINCE THAT TIME. NO PATIENTS HAVE BEEN DONE UNDER THE NUCLEAR LICENSE.

THE BOARD OF TRUSTEES OF STARKE MEMORIAL HOSPITAL IS PRESENTLY REVIEWING THE NUCLEAR PROGRAM AN WILL SUBSEQUENTLY MAKE A DETERMINATION AS TO WHETHER TO CONTINUE WITH THE NUCLEAR LICENSE. IN THE MEANTIME, NO NUCLEAR MEDICINE PATIENTS ARE BEING DONE WITHIN THE HOSPITAL AND THE HOT LAB HAS BEEN SECURED.

BECAUSE OF THE ABSENCE OF AN ACTIVE NUCLEAR MEDICINE PROGRAM WITHIN THE HOSPITAL, THE HOSPITAL HAS STARTED USING A MOBILE NUCLEAR SERVICE PROVIDED BY MIDWEST MOBILE IMAGING. AT PRESENT, THE SCANNER IS ON SITE ON TUESDAYS TO DO THE NUCLEAR PATIENTS. THIS NUCLEAR SERVICE DOES NOT REQUIRE STARKE MEMORIAL HOSPITAL TO MAINTAIN A NUCLEAR MEDICINE LICENSE.

LORI CAPUTO INDICATED THAT IN AUGUST A LICENSE RENEWAL FEE OF $1,800.00 WILL BE DUE TO THE N.R.C. IF THE HOSPITAL DECIDES TO CONTINUE WITH THE NUCLEAR LICENSE. A FORMAL DECISION WILL BE MADE BY ADMINISTRATION AND THE BOARD OF TRUSTEES BEFORE THIS TIME TO DETERMINE WHETHER TO DECERTIFY THE NUCLEAR LICENSE OR TO CONTINUE WITH THE PROGRAM.

THERE HAVE BEEN NO MIS-ADMINISTRATIONS OR RADIOACTIVE SPILLS IDENTIFIED IN THE PRESENT QUARTER.

RESPECTFULLY SUBMITTED,

Richard A Boyd M.D.

RICHARD A. BOYD, M.D.
RADIATION SAFETY OFFICER
STARKE MEMORIAL HOSPITAL

CC: KATHY NOREM
LORI CAPUTO
DR. BOYD
FILE

minutes from last meeting 7/8/96 to follow

RADIATION SAFETY COMMITTEE MINUTES

STARKE MEMORIAL HOSPITAL

DATE: TUESDAY, MARCH 5, 1996

PLACE: CONFERENCE ROOM

PRESENT: DR. BOYD, RADIATION SAFETY OFFICER; MRS. KATHY NOREM, R.N., CHIEF EXECUTIVE OFFICER OF STARKE MEMORIAL HOSPITAL AND LORI CAPUTO, CHIEF OF DIAGNOSTIC SERVICES.

ABSENT: NONE

PREVIOUS MINUTES: MINUTES OF THE PREVIOUS MEETING WERE NOT AVAILABLE AND WILL BE REVIEWED AT THE NEXT RADIATION SAFETY COMMITTEE MEETING.

NEW BUSINESS:

BADGE REPORTS ON ALL EMPLOYEES INDICATE READINGS BELOW 10% OF MAXIMUM PERMISSIBLE DOSE AS RECOMMENDED IN THE ALARA PROGRAM.

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THERE HAVE BEEN NO MIS-ADMINISTRATIONS OR RADIOACTIVE SPILLS IDENTIFIED IN THE PRESENT QUARTER.

RESPECTFULLY SUBMITTED,

Richard A Boyd M.D.

RICHARD A. BOYD, M.D.
RADIATION SAFETY OFFICER
STARKE MEMORIAL HOSPITAL

CC: KATHY NOREM
LORI CAPUTO
DR. BOYD
FILE

RECEIVED MAR 0 1 1996

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

3/4/96
CC Dr. Boyd
Gave to Loretto
Then file
in admin.

February 27, 1996

Kathy Norem
Chief Executive Officer
Starke Memorial Hospital
102 East Culver Road
Knox, IN 46532

Dear Ms. Norem:

This refers to the inspection conducted on January 26, 1996 (with continued NRC in-office review through February 13, 1996), at Starke Memorial Hospital, Knox, Indiana. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with Richard Boyd, M.D. by telephone on February 13, 1996.

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.

No violations of NRC requirements were identified during the course of this inspection.

One concern was identified involving the use of a dose range on a written directive. It is our understanding that you will ensure that dose ranges will not be used on written directives. Therefore, no written response to this concern is requested.

Lori, Has this been addressed? Kathy

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter will be placed in the NRC Public Document Room.

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

Sincerely,

Robert G. Gattone Jr.
Robert G. Gattone, Jr.
Radiation Specialist

3/5/96 documented in 1st Qtr mtg minutes. Lori

License No.: 13-15399-01
Docket No.: 030-09044

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 6, 1996

STARKE MEMORIAL HOSPITAL
ATTN: DR. RICHARD A. BOYD, M.D.
Radiation Safety Officer
RADIOLOGY AND NUCLEAR MEDICINE
102 EAST CULVER ROAD
KNOX, IN 46532

SUBJECT: ONE-TIME EXTENSION OF LICENSE EXPIRATION DATE
LICENSE NUMBER 13-15399-01 DOCKET NUMBER 3009044

Dear DR. RICHARD A. BOYD, M.D.

On January 16, 1996, the Nuclear Regulatory Commission (NRC) amended its regulations in 10 CFR 30, 40, and 70 to extend the expiration date of certain byproduct, source, and special nuclear material licenses by five years (61 FR 1109). The above referenced license was extended by this rulemaking and will now expire on May 31, 2004. Your license will not be amended to show this extended date until the next routine licensing action. Until then, you may provide copies of this letter to vendors and other interested parties as evidence that the license has been extended as a result of the rule.

The extended license authorizes the same activities and contains the same limitations as it previously did. There will be no change in the frequency that the NRC inspects activities authorized by this license.

The amended rules state that in the case of licensees who are granted extensions and who have a currently pending renewal application for that extended license, the application will be considered withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded. This will apply to licenses with expiration dates after July 1, 1995, for which renewal applications and the appropriate fees have been submitted and the renewal is still pending. Refunds will be mailed to licensees under separate cover.

All licensees, including those whose renewal applications were withdrawn by this rulemaking, who wish to change their radiation safety programs must request amendment of their licenses to reflect these changes. Amendment requests must include the correct amendment fee since the NRC cannot apply pending renewal refund balances toward amendment fees.

If you have any questions regarding this letter, please contact the individual below.

John R. Madera, Division of Nuclear Materials Safety - (708) 829-9834

Thank you for your cooperation in this matter.

Sincerely,

Donald A. Cool, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards

RADIATION SAFETY AUDIT
NUCLEAR MEDICINE INSPECTION

I. Licensee: Starke Memorial Hospital

II. Address: Knox, IN

III. License No. 13-15339-01 Expiration Date: May 31, 1998

IV. Date of Audit March 12, 1996

V. Auditor(s): Stu W. Burk

VI. Inspection Findings:

The inspection was an examination of the activities conducted under the above license as they relate to radiation safety and to compliance with the NRC or Illinois Department of Nuclear Safety rules and regulations, 32 IL Adm. Code, and the conditions of the above radioactive materials license. The inspection included as appropriate: selective examinations of procedures and representative records, interviews with personnel, observations, and confirmatory measurements. Note: this audit covers the records from 3/15/95 to 1/16/96. Nuclear Medicine studies have not been performed since that time.

A. Posting of Notices and Signs:

1. Rooms or areas were properly posted to indicate the presence of a Radiation Area.
Yes ____ No ____ N/A X [10 CFR 20.203 (b)]
Comments:

2. Rooms or areas were properly posted to indicate the presence of a High Radiation Area.
Yes ____ No ____ N/A X [10 CFR 20.203 (c)]
Comments: _____

3. Rooms or areas were properly posted to indicate the presence of an Airborne Radioactivity Area.
Yes ____ No ____ N/A X [10 CFR 20.203 (d)]
Comments: _____

4. Rooms or areas were properly posted to indicate the presence of Radioactive Material.
Yes X No N/A [10 CFR 20.203 (e)]
Comments: _____

5. Containers were properly labeled to indicate the presence of Radioactive Material.
Yes X No N/A [10 CFR 20.203 (f)(1) or (f)(2)]
Comments: _____

6. A copy of the regulation "Notices, Instructions and Reports to Workers, Inspections" was properly posted for use by the individual participating in the licensed activities. [10 CFR 19.11(a)(1)]
Yes X No ____ N/A ____ (See A.11)

7. A copy of the regulation "Standards for Protection Against Radiation" was properly posted for use by the individuals participating in the licensed activities. [10 CFR 20, 10 CFR 19.11(a)(1)]
Yes ____ No ____ N/A X (See A.11)

8. Copies of the current license, license conditions, and amendments thereto were properly posted. [10 CFR 19.11(a)(2)]
Yes ____ No ____ N/A X (See A.11)

9. Copies of the documents incorporated into the current license by reference were properly posted. [10 CFR 19.11(a)(2)]
Yes ____ No ____ N/A X (See A.11)

10. A copy of the operating procedures applicable to licensed activities was properly posted. [10 CFR 19.11(a)(3)]
Yes ____ No ____ N/A X (See A.11)

11. Postings of documents specified in A.6-10 was not practicable; therefore, the licensee posted a notice that describes the documents and states where they may be examined. [10 CFR 19.11(b)]
Yes X No ____ N/A ____
Comments: _____

12. Form NRC-3 "Notice to Employees" was posted in a sufficient number of places for use by the individuals who work in or frequent any portion of the restricted area. [10 CFR 19.11(c)]
Yes X No N/A
Comments: Posted on entrance door.

13. A copy of any notice of violation issued by the NRC involving radiological working conditions was posted within five (5) working days after the receipt of such notice for a minimum of five (5) working days, or a notice stating that all correspondence to/from the NRC can be examined in the Radiation Safety Office.

Yes ____ No ____ N/A X
Comments: _____

Date of previous NRC inspection: January 26, 1996

Violations found during previous inspection: There were no violations found.

Have previous violations been corrected?: Not Applicable

B. Records and Reports

1. Records of current occupational radiation exposures of individuals were properly maintained on Siemens monthly film badge reports.
Yes X No ____ N/A ____
Comments: _____

2. Records of individual total accumulated occupational dose were maintained for each radiation worker on Siemens monthly reports.
Yes X No ____ N/A ____
Comments: _____

3. Summary of radiation exposure values for past year:

	1st Qtr '95		2nd Qtr '95		3d Qtr '95		4th '95	
	Neutron	Radiation	NM	Rad	NM	Rad	NM	Rad
# of persons <10% :	2	16	2	15	1	16	1	16
# >10% but <30% :	0	0	0	0	0	0	0	0
# >30% but <MPD :	0	0	0	0	0	0	0	0
# > MPD :	0	0	0	0	0	0	0	0

Have exposure results above action levels or limits been properly evaluated by RSO, discussed by RSC, and required reports filed (if applicable)? Yes X No ____ N/A ____
Comments: _____

4. Records of radiation surveys of all working areas where the licensed material is used were maintained.
Yes X No N/A

a. Frequency of survey:	Daily	Weekly	Monthly
1. Elution, preparation and/or injection area	X		
2. Other lab areas	X		
3. Rad waste storage	X		
4. Other:			

b. Date of last survey: 1/15/96, survey results checked:
c. Comments:

5. Records of radiation contamination wipe test of all working areas where the licensed material is used were maintained.
Yes X No N/A

a. Frequency of wipe tests:	Daily	Weekly	Monthly
1. Elution, preparation and/or injection area		X	
2. Other lab areas		X	
3. Rad waste storage		X	
4. Other:			

b. Date of last wipe: 1/15/96
c. Comments:

6. Records of disposal of licensed radioactive material were properly maintained.
Yes X No N/A
Frequency of disposal: Previous disposal was in 1993
Date of last disposal: The remaining waste were disposed on this date, 3/12/96 and recorded in the disposal file.
At least 10 half-lives elapsed? Yes

7. Records of receipt of licensed material were properly maintained.
Yes X No N/A
Records of survey at 1 meter: X surface: X
wipe of final source container: Yes
survey of box before discard: N/A
defacing of labels before discard: N/A
Comments: The boxes are returned to the supplier.

8. Records of transfer of licensed material were properly maintained.

Yes X No N/A

Date of transfer: Yes

Identity of materials transferred: Yes

9. Records of leak tests were maintained as prescribed in the license.
Yes X No N/A

	Sealed Source (Isotope/SN)	Required Frequency	Date of Leak Test	Date Next Due
a.	Cs-137/356018041-10	semi-annual	10/3/95	March 1996
b.		semi-annual		
c.	____/____			
d.	____/____			
e.	____/____			
f.	____/____			
g.	____/____			

Comments:

10. Records of isotope inventories were properly maintained to comply with possession limits.
Yes X No N/A

Date of Previous Inventory: 12/26/95 Required Frequency: Quarterly
Comments:

11. Utilization logs of each isotope received were properly maintained.
Yes X No N/A
Comments:

Records include:

a. Radionuclide X

b. Generic or trade name (i.e.: MDP, pyrolite) X

c. Date received X

d. Supplier X

e. Lot # X

f. Activity and cal. time of the unit dose (supplier's record) ✓

g. date of administration or disposal X

If administered to a patient:

h. Prescribed dose: (on list or in procedure manual) X

i. measured activity in units of mCi or uCi X

j. date and time of measurement X

k. patient name and I.D. # (if assigned) X

l. initials of the person who made the record X

12. Records of calibration of radiation survey instruments as required by the conditions of the license were properly maintained.
Yes X No ____ N/A ____

	Instrument (Model/SN)	Required Frequency	Date of Calibration	Date Due
a.	14C / 52745	Annual	10/3/95	10/96
b.	CDV700 / 968506	Annual	10/3/95	10/96
c.	____/____	____	____	____
d.	____/____	____	____	____
e.	____/____	____	____	____
f.	____/____	____	____	____

Comments: ____

13. Records of bioassay tests were maintained on all individuals as required by conditions of the license.
Yes ____ No ____ N/A X

	Name	Date of Bioassay	Results
a.	____	____	____
b.	____	____	____

Comments: There have been no materials used requiring a bioassay.

14. Records and results for determining airborne concentration of radioactive material in working areas were properly maintained.
Yes X No ____ N/A ____
Comments: ____

Previous measurements of air exhaust flow rates: 10/3/95 and today.

15. Records and results for determining concentrations of radioactive material released into the sanitary sewer system were properly maintained.

Yes ____ No ____ N/A X

Comments: There is no sewage disposal.

16. Records and results of dose calibrator calibration were maintained as prescribed in the license.

Yes X No ____ N/A ____

Calibrator (Model/SN)	Daily Constancy	Annual Accuracy	Quarterly Linearity
CRC15R/150084	1/15/96	3/15/95	12/26/95

Geometric Variation: 4/26/94

RSO sign?: Yes Yes Yes

Comments: ____

17. Records and results of dose calibrator molybdenum breakthrough tests were maintained as prescribed in the license.

Yes ____ No ____ N/A X

Comments: Generators have not been used during the past year.

18. Records and results of Xenon leakage from charcoal trap units were maintained as prescribed in the license.

Yes X No ____ N/A ____

Frequency of efficiency tests Current up to 12/19/95.

Comments: Would need to be repeated again before first use of Xe-133

C. Operating Procedures and Manuals

1. The institutional radiation safety program for all radiation workers and ancillary employees is operational and effective.

Yes X No ____ N/A ____

Group Instructed	Dates of Radiation Safety Instruction
Ancillary Personnel	January 1995
Ed Dubbs, Technologist	10/3/95

2. Procedures are in effect that ensure that work is performed only by authorized personnel.
Yes X No N/A
Comments: _____

3. A radiation safety procedures manual is written and copies are made available for the use of all the radiation workers, and personnel who come in contact with radioactive material.
Yes X No N/A
Comments: _____

4. Radionuclide dosages for each diagnostic procedure are included in the procedure manual or are posted in the nuclear medicine lab Yes

The dosage list is signed by an authorized user Yes

Dosages administered are within +/- 10% of the prescribed range: Yes

Number or dates reviewed: 3 months

Number of cases or % of cases outside +/- 10%: 0

5. Prescriptions by an authorized user for all radionuclide therapy cases are maintained: Yes

6. Procedures for picking up, receiving, and opening packages containing radioactive material are available and are in routine use.
Yes X No N/A
Comments: _____

7. There are requirements for protective security of all radioactive areas from unauthorized personnel.
Yes X No N/A
Comments: _____

8. The Radiation Safety Committee meetings are held at periodic intervals to review the radiation safety program at the institution. Required meeting frequency: Quarterly

Yes X No N/A

Comments: Dates of most recent meeting(s): March 5, 1996

9. Summary of amounts, activities, used or in possession during past year:

Radionuclides	Activities	Comments
^{99m}Tc	4.6 Curies in 1995	
^{133}Xe	182 mCi in 1995	
^{201}Tl	92 mCi in 1995	
^{111}In	2.5 mCi in 1995	
^{131}I	25 mCi in 1995	
^{123}I	2.5 mCi in 1995	

All use within possession limits? Yes X No N/A

D. Personnel

1. Written authority for all non-physicians who administer radiopharmaceuticals is maintained.

Yes X No N/A

Comments:

2. Records of nuclear medicine accreditation for all technologists are maintained.

Yes X No N/A

Comments:

3. All personnel have reviewed the ALARA program and are familiar with the ALARA philosophy:

Yes X No N/A

E. This audit was completed by: _____

_____

Reviewed by: _____
Radiation Safety Officer

_____
Chairman, Radiation Safety Committee

F. Administrative Actions

1. Items of noncompliance or unsafe conditions were found.
Yes ____ No X N/A ____
Comments: _____

2. The following items of noncompliance related to each of the above sections were found:
Section A: N/A

Section B: N/A

Section C: N/A

Section D: N/A

Reviewed by: _____ (administrative representative)

_____

QUALITY MANAGEMENT PROGRAM AUDIT
NUCLEAR MEDICINE DEPARTMENT INSPECTION

I. Licensee: Starke Memorial Hospital

II. Address: Knox, IN

III. License No. NRC: 13-15339-01 Expiration Date: 5/31/99

IV. Date of Audit: March 12, 1996

V. Auditors: Stf W Bth

Quality Management Program Audit Ref: NRC Regulations 10 CFR 35.32
NRC Regulatory Guide 8.33

1. Diagnostic Clinical Procedure Manual:

There is a collection of written procedures for all diagnostic studies that i available to all nuclear medicine personnel. The manual contains;

a description of each procedure Yes X No____

the radiopharmaceutical to be administered Yes X No____

the dosage range to be administered Yes X No____

the route of administration Yes X No____

the approval and signature of an authorized physician user who is named on the NRC license Yes X No____

2. Therapeutic Radiopharmaceuticals (I-131 (Sr-89) and P-32, and I-125 or I-131 sodium iodid administrations of greater than 30 uCi activity:

Written Directives for all therapeutic administrations of I-131 (Sr-89) or P-32, an for diagnostic administrations of greater than 30 uCi of I-125 or I-13 sodium iodide are on file;

No. of procedures performed requiring a written directive 2

No. of written directives on file 2

Do each of the written directives contain the following information:

signature of authorized user Yes X No___

date Yes X No___

the patient's name Yes X No___

the date Yes X No___

the radiopharmaceutical Yes X No___

the dosage Yes X No___

the route of administration Yes X No___

As discussed at the June 5, 1 RSC meeting, the dosage is to a specific amount, not a range as noted on the 3/16/ written direct,

NOTE: Revisions to the written directive may be made in compliance with the footnote to 10 CFR 35.32(a)(1).

3. Patient Identification:

Prior to administration of a radiopharmaceutical, the identity of the patient is to be verified by more than one method. Do records indicate that one of the following was used, in addition to asking the patient his/her name, prior to administration of a radiopharmaceutical under the requirements of the QMP;

birth date	Yes___	No___
address	Yes___	No___
Social security number	Yes X	No___
signature	Yes___	No___
identification bracelet	Yes X	No___
hospital I.D.	Yes___	No___
medical insurance card	Yes___	No___
drivers license	Yes X	No___

4. Verification of Proper Radiopharmaceutical:

Prior to administration of a radiopharmaceutical, specific details of the administration must be verified to confirm they are in agreement with the written directive. Is there documentation that the following details are documented;

correct radiopharmaceutical Yes X No___

correct dosage (dose calibrator reading must be within +/-10% of directive) Yes X No___

route of administration Yes X No___

5. Documentation of Dosage: Refer to 10 CFR 35.32 (d)(2)

After administration of the dosage, a record of the dosage given must be signed by one or more of the following persons:

an authorized user who is listed on the license Yes X No___

another nuclear medicine physician, a physicist or technologist under the supervision of an authorized user Yes X No___

6. Misadminstrations:

A summary of misadministrations (refer to 10 CFR 35.2 definitions and 10 CFR 35.33 reporting requirements)

Comments: There were no misadministrations or recordable incidents found. The 3/16/95 written directive used a range, rather than specific amount and this was documented at the time of the 6/15/95 RSC meeting.

Respectfully submitted,

Steve W. Bahn

Reviewed by:_____ Date:_____

Reviewed by:_____ Date:_____

Calibration to be done annually. That N.M. Exam done 1/16/96. N.M. Tech assigned that day.

DOSE CALIBRATOR
ACCURACY/CALIBRATION CERTIFICATE

Standard Nuclear Consultants (708) 365-5858

P.O. Box 362, Manhattan, IL 60442 □ 1S016 Donny Hill Road, Elburn, IL 60119

LICENSEE: Starke Memorial Hospital, Knox, IN

DATE: March 15, 1995 CALIBRATED BY: D.W. Burk

INSTRUMENT MANUFACTURER: Capintec

MODEL # / SERIAL #: CRC 15R / 150084

ACCURACY RESULTS

Reference Standard	Radionuclide Setting	Source Activity	Observed Activity	Percent Accuracy	Correction Factor
1 ^{57}Co	^{57}Co	1.28 mCi	1.30 mCi	1.6%	—
2 ^{133}Ba	^{133}Ba	118 uCi	121 uCi	2.5%	—
3 ^{137}Cs	^{137}Cs	174 uCi	177 uCi	1.7%	—
4					
5					

CROSS CHECK OF COMMONLY USED RADIONUCLIDE SETTINGS

6	^{57}Co	^{99m}Tc	1.28 mCi	1.55 mCi	X1.21	—
7	^{137}Cs	^{99}Mo	174 uCi	217 uCi	X1.25	—
8	^{137}Cs	^{67}Ga	174 uCi	292 uCi	X1.68	—
9	^{137}Cs	^{201}Tl	174 uCi	187 uCi	X1.07	—
10	^{57}Co	^{133}Xe	1.28 mCi	.937 mCi	X.73	—
11	^{57}Co	^{123}I	1.28 mCi	.705 mCi	X.55	—
	^{133}Ba	^{131}I	118 uCi	350 uCi	X2.97	—

A. Accuracy results (are) / ~~are not~~ within ± 5% limits. —

B. Cross check results (do) / ~~do not~~ agree with previous results.

C. Constancy results (are) / ~~are not~~ within ± 5%. —

D. Linearity results (are) / ~~are not~~ within ± 5%. —

E. Geometrical variation (is) / ~~is not~~ within ± 2%. —

Next Calibration Due: March 1995

Radiation Safety Officer signature: Richard A Boyd MD.

STANDARD NUCLEAR CONSULTANTS
1S016 DONNY HILL ROAD
ELBURN, ILLINOIS 60119

IDNS License No.: IL-01300-01

Leak Test Report
For Radioactive Sources

Date: March 12, 1996

Licensee: Starke Memorial Hospital

Address: Knox, IN

License #: 13-15339-01

Radioactive Source Information

Source: Cs-137
Activity: 200 uCi
As Of: January 1980
Manufacturer: NEN
Model #: NES-356
Serial #: 3560180A-10
Leak Test Date: 3/12/96
Collected by: Stan Buhr

Results:

Gross cpm: 64
Background cpm: 60
Net cpm: 4
uCi removable: <0.005 uCi

Note: Sensitivity of counting instrument is <0.0005 uCi.

Conclusion: Radioactive leakage from source is <0.005 uCi.

Analyzed by: Stan W. Buhr Date: 3/12/96

Next Leak Test Due: September 1996

Radiation Safety Officer: _____

SEALED SOURCE INVENTORY

Licensee: Starke Memorial Hospital Address: Knox, IN

	SOURCE/DEVICE	QUANTITY & KIND OF BYPRODUCT MATERIAL	Activity and LOCATION OF SOURCE/DEVICE	INITIALS	DATE OF INVENTORY
①	^{137}Cs NEN DuPont	Vial, Model NES-356 #3560180 A-10	200 uCi on 1/25/80 In Hot Lab		
②	^{133}Ba ICN	Model MLO-01 SWO# 189649B	270 uCi on 6/18/85 In Hot Lab		
③	^{137}Cs NEN DuPont	Glass vial containing green epoxy # 80231080 A-60	30.8 uCi on 10/10/80 In Hot Lab		
④	^{137}Cs Nuclear Chicago	Model 184020 plastic tube	0.57 uCi on 4/66 In Hot Lab		
Sources ①②③④		Present/Accounted for	"	AB	7/8/96

RSO

SEALED SOURCE INVENTORY

Licensee: Starke Memorial Hospital Address: Knox, IN

	SOURCE/DEVICE	QUANTITY & KIND OF BYPRODUCT MATERIAL	LOCATION OF SOURCE/DEVICE	INITIALS	DATE OF INVENTORY	R.S.O
1.	^{137}Cs (NEN)	Vial E, Model NES-356 Sn 3560BDA-10	200 μCi on 1-25-80 HOT LAB	RB	3-16-91	RB
2.	^{133}Ba (ICN)	SWO #189649B	270 μCi on 6-18-85 Transferred to Hot Lab on Basement Storage	RB	3-16-91	RB
3	^{137}Cs (NEN)	Vial # 80231080A-60	30.8 μCi on 10-10-80 HOT LAB	RB	3-16-91	RB
4.	^{137}Cs (Nuclear Chicago)	Model 184020 plastic tube	0.57 μCi on 4/66 HOT LAB	RB	3-16-91	RB
	①②③④	Accounted for.	"	RB	6/17/91	RB
	①②③④	Accounted for.	"	RB	9/16/91	RB
	①②③④	Accounted for	"	RB	12/16/91	RB
	①②③④	Accounted for	"	BK	3/3/92	BK
	①②③④	Accounted for	"	RB	6/26/92	RB
	①②③④	Accounted for	"	RB	9/15/92	RB
	①②③④	Accounted for	"	RB	12/1/92	Rudolph
	①②③④	Accounted for	"	Stolw Bdl	3/9/93	Rudolph
	→ #2 NOW LOCATED IN HOT LAB -					
	①②③④	Accounted for	(All in Hot Lab	Stolw Bdl	6/10/93	RBrydon
	①②③④	Accounted for	(All in Hot Lab)	Stolw Bdl	9/2/93	RBrydon
	①②③④	Accounted for	(All in Hot Lab)	Stolw Bdl	12/2/93	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	3/3/94	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	6/2/94	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	9/1/94	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	12/8/94	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	3/15/95	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	6/5/95	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	10/2/95	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	12/26/95	RBrydon
	①②③④	Accounted for	All in Hot Lab	Stolw Bdl	3/12/96	RBrydon

STANDARD NUCLEAR CONSULTANTS
P.O. BOX 362
MANHATTAN, IL 60442

(708) 365-5858 FAX: (815) 478-5419

March 12, 1996

Lori Caputo
Laboratory
Starke Memorial Hospital
102 East Culver Road
Knox, Indiana 46534

Dear Ms. Caputo:

Following is the summary of my March 12, 1996 visit to the Starke Memorial Hospital nuclear medicine facilities.

RADIATION SAFETY COMMITTEE:

The quarterly Radiation Safety Committee meeting was held last week and the minutes were typed. I recommended that the member present and members absent be added to the minutes to comply with the Part 335 rules. I also recommended adding a statement that the film badge reports were reviewed and found below the ALARA action levels.

NRC LICENSE:

We discussed the steps involved if a decision would be made to discontinue nuclear medicine services and cancel the NRC license. At this time, you indicated the license will be continued and attempts will be made to find a part time technologist to offer nuclear medicine procedures when needed.

The license amendment to add Dr. Sharma as a physician user was issued by the NRC on 10/26/95. There are no further changes needed at this time.

The NRC has now approved the proposal to extend licenses for an additional 5-year period without a renewal application and renewal fee. The change was approved 1/15/96 and became effective 2/15/96. The hospital will be eligible for the automatic renewal if there are no outstanding violations or enforcement actions pending at that time.

In the meantime, changes to the license should be made by separate amendment application, not with the renewal, as the renewal application will likely not be reviewed.

The NRC is planning major revisions to the methods of licensing medical users, and the above proposal would free up necessary staffing time to complete this project. The changes may include a computerized system which would greatly speed the turnaround time for applications.

The NRC also recently sent the planned fee schedule for 1996 - 1997. It is nearly the same as last year except that the amendment fees are raised from $430 to $440 (effective in August), the renewal fee is not specified (as most hospitals will not need to pay it) and the annual maintenance fee is decreased from $4700 to $4300. In your case, the small entity fee of $1800, for government hospitals, will still apply.

REGULATORY ITEMS:

The EPA Clean Air Act calculations are still be required this year. I completed the calculations based on the total activities used in 1995. A report does not need to be submitted to the EPA, but this worksheet is to be maintained for possible inspection during the next NRC visit.

The NRC has also prepared a draft regulatory guide on the subject of air concentrations of radioactive materials. For the past several years, the EPA has been involved because it did not feel the NRC was doing enough to regulate potentially airborne materials. This guide may be a step towards having the EPA again assigning all regulation of air concentrations of radioactive materials to the NRC.

The NRC notices concerning intentional exposure of workers in research labs have been followed up by requirements for reporting any such incidents of "intentional diversion" of radioactive materials (and cases where intentional diversion cannot be ruled out). There is also a Federal Register proposal to include reporting of exposure of the embryo/fetus if the radiation exposure is above a certain action level.

Posting in the department was found in compliance with applicable regulations.

In followup to new NRC/DOT rules concerning training and monitoring of drivers who transport radioactive materials, several radiopharmacies have sent the hospitals letters stating these employees have been trained, in accordance with the new regulations.

The NRC had recently commissioned the National Academy of Sciences to complete a study of the role of the NRC in regulating medical users of radioactive materials. The NRC is now reviewing the recommendations of the NAS, including:

(a) immediately relax enforcement of Quality Management Programs, 10 CFR 35.22 and 35.25

(b) NAS recommended that Congress eliminate the NRC from regulation of medicine altogether, replaced by HHS support to State health departments, and giving the States the immediate authority to regulate reactor produced radioactive materials

(c) OAS favors continued involvement by NRC, but discontinuing regulating any functions dealing with the practice of medicine,

(d) requiring that "bioeffects" be used in evaluating regulations, considering the overall risk involved.

(e) current revision of Part 35 is to be placed on hold until congress acts on the NAS recommendations

INSPECTIONS:

The NRC inspection of the hospital was held on 1/26/96 and the visit went very well, with no violations listed on the official summary. There were several items which he discussed verbally, but were not included on the report:

- The most leak test certificate could not be located during the visit. This was located today on the bookshelf in the camera room. It was apparently left out by the previous technologist for signing by the RSO.

- Use of a range, rather than a specific amount for an I-131 treatment. This had been discussed in previous RSC meetings and was already corrected. This was likely not cited by the NRC because it was already self-identified.

- The most recent set of RSC minutes did not reflect the members present and members absent and did not include a discussion of film badge results in comparison to ALARA action levels. (The 10/5/95 minutes were not seen by the inspector, as they were filed in the 3-ring binder in nuclear medicine. These did include the required information.)

- The inspector was apparently concerned about the broken Pb-shield for the Cs-137 vial source used for dose calibrator checks. The inspector took leak tests of the source and on the phone indicated there is no leakage. I had also previously done leakage tests, after the source was damaged and confirmed no leakage. At that time, I had discussed this problem with the NRC by telephone and was told no further action was needed. This incident is discussed in detail in my 9/2/93 report, under the Leak Test category and in Item #14 of the 9/2/93 RSC minutes.

ALARA RADIATION SAFETY PROGRAM:

1. We reviewed film and TLD badge results for nuclear medicine and radiology personnel and found them to be well below 10% of the EDE limit, as recommended by the NRC ALARA program.

2. I completed the annual radiation safety ALARA audit on this date. Each of the required records in nuclear medicine was reviewed and found complete. The most recent procedures were conducted 1/16/96 and all records have been put on hold since that time.

3. I also completed the annual Quality Management Program audit on this date and this will need to be reviewed and signed along with the ALARA audit. All the required information, including written directives, patient identification and dosage verification were found to be in compliance. The one item which was not in total compliance was the 3/16/95 thyroid therapy dosage which was listed as 15 - 16 mCi on the written directive. This had been previously discussed in March 1995.

4. Before conducting lung ventilation tests in nuclear medicine again, it will be necessary to repeat the required semi-annual ventilation checks in the camera room.

5. I updated the quarterly physical inventory of sealed sources on this date and all were accounted for.

6. Dr. Boyd will need to sign the January 15, 1996 survey records which are located in the white 3-ring binder in nuclear medicine.

LEAK TESTS:

I performed the semi-annual leak test on the Cesium-137 dose calibrator check source and the certificate will be mailed for the nuclear medicine records.

INSTRUMENT QUALITY CONTROL:

Day-of-use constancy records on the dose calibrator were found to be within +/- 5% ranges. I recorded the new dose calibrator constancy ranges for each setting, to account for one year of decay of the Cs-137 source.

I did not complete a quarterly linearity check on the dose calibrator today, but this would need to be repeated before procedures are reinitiated. The accuracy tests on the dose calibrator will also need to be completed before procedures are performed.

I performed the operational checks on the survey instruments. Results indicated they are operating properly and in accordance with regulatory standards.

Gamma camera quality control through the time the procedures were suspended were up to date and indicate the instrument is operating properly.

Thank you. Our next visit will be scheduled for June 1996. In the meantime, please contact us if questions arise.

Sincerely,

Stan Buhr, Health Physics Consultant

September 19, 1996

VIA FACSIMILE and U.S. MAIL

Mr. John Madera
Chief - Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
801 Warrensville Road
Lisle, Illinois 60523-4351

Re: Change of Leaseholder
Starke Memorial Hospital

Dear Mr. Madera:

I am writing to notify your office of the proposed change in Leaseholder of Starke Memorial Hospital, a County Hospital organized pursuant to the Acts of 1917, Chapter 144, located in Knox, Indiana (the "Hospital").

As currently proposed, the Hospital will be leased by Principal Hospital Company. The parties currently anticipate that this transaction will become effective on or about October 1, 1996.

The Hospital currently has a license issued by your branch, license number 13-15399-01.

By way of this letter, I request that your office send all necessary licensure forms to document this change of ownership to me at the above address. The executed licensure forms reflecting this transaction will then be submitted to your office prior to the change of ownership. The bill of sale evidencing the transaction will be forwarded to you upon the close of the transaction.

Please let me know if you need any additional information at this time. My direct number is 615/252-2406.

Yours truly,

Kellie A. Little
Paralegal

cc: Mr. Martin Rash
Kevin D. Norwood, Esq.
Michelle B. Marsh, Esq.

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

WALLER LANSDEN DORTCH & DAVIS
ATTN: KELLIE A. LITTLE
PARALEGAL
511 UNION STREET SUITE 2100
POST OFFICE BOX 198966
NASHVILLE, TENNESSEE 37219-8966

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 9-26-96

LICENSE NUMBER: 13-15399-01

CONTROL NUMBER: 301881

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$	$ 440.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(S) DUE	$ 440.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 440.00

- ☒ Your request was received without the prescribed application fee.
- ☐ We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.
- ☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- ☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.
- ☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
Shirley Crutchfield	SC	
SHIRLEY CRUTCHFIELD	10/7/96	

Distribution: OC/DAF/RF
Pending Fee File OC/DAF/SF(LF-3.2.7)
LFARB R/F (2) Region 3

DATE: Oct. 9, 1996

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

OCT 16 1996

Richard A. Boyd, M.D.
Radiation Safety Officer
Principal Knox Company
d/b/a Starke Memorial Hospital
102 East Culver Road
Knox, IN 46532

Dear Dr. Boyd:

This refers to the letters dated September 17, 1996 and September 26, 1996, requesting NRC consent to the proposed transfer of control of Starke Memorial Hospital, NRC License No. 13-15399-01. Based on the information submitted in the letters, the NRC has no objection to the transfer of control.

Enclosed is Amendment No. 12 to your NRC Material License No. 13-15399-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

301881

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

   b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b) to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

License No. 13-15399-01
Docket No. 030-09044

Enclosure: Amendment No. 12

cc: Chief Executive Officer
Principal Knox Company
d/b/a Starke Memorial Hospital
102 East Culver Road
Knox, IN 46532

Ms. Kellie A. Little
Paralegal
Waller Lansden Dortek & Davis
511 Union Street, Suite 2100
P.O. Box 198966
Nashville, TN 37219-8966

DOCUMENT NAME: M:\03009044.CL6
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	C							
NAME	MFWEBER:sjd								
DATE	10/15/96								

OFFICIAL RECORD COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME	DATE
11:45 am	10/8/96

○ VISIT ○ CONFERENCE X TELEPHONE

NAME OF PERSON(S) CONTACTED	ORGANIZATION (OFFICE, DEPT, ETC.)	TELEPHONE NO.
Kellie A. Little, Paralegal	Waller Lansden Dortch & Davis	615-252-2406

SUBJECT

Leasing of Starke Memorial Hospital - Control No. 301881 - Lic. No. 13-15399-01

SUMMARY

I asked about the 9/17/96 letter which referred to "leasing" the hospital, but also mentioned a "bill of sale." Ms. Little said that the hospital was being leased, and not sold, and that the use of "bill of sale" in the referenced letter was incorrect.

ACTION REQUIRED

Issue amendment.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Michael F. Weber	M. F. Weber	10/10/96

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 30, 1996

Richard A. Boyd, M.D.
Radiation Safety Officer
Principal Knox Company
d/b/a Starke Memorial Hospital
Radiology and Nuclear Medicine
102 East Culver Road
Knox, IN 46532

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE (Letter Dated 09/26/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License X Amendment ___ Renewal

Administrative deficiencies were identified during this initial review as outlined below. However, it should be noted that a technical review may identify additional omissions in the submitted information.

It appears that your request is routine (see 1-3 below as, applicable).

Incomplete information is as follows: An amendment (with the required fee) is necessary to change the name of your company. Please contact our License Fee & Debt Collection Branch, located in our headquarters office, as referenced below, to otain the correct fee amount.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however under timely filing (before expiration) you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301881
License No. 13-15399-01