

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

35-19898-01

Docket or Reference number

Amendment No. 01

City of Faith Medical and Research
Center
8181 S. Lewis
P.O. Box 3600
Tulsa, Oklahoma 74136

In accordance with telegram dated March 2, 1982, License Number 35-19898-01
is amended as follows:

TO ADD:

- | | | |
|---|--|--|
| 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 |
| F. Strontium 90 | F. Sealed source (ICN Catalog No. 75144) | F. 100 millicuries |
-
9. Authorized use
- F. Storage Only.

Date

MAR 04 1982

For the U.S. Nuclear Regulatory Commission

PW 4-82

Original Signed By
Patricia S. Vaeda
Material Licensing Branch

By

Division of Fuel Cycle and
Material Safety
Washington, D.C. 205558507270131 850624
PDR FOIA
HARGROVE85-341 PDR

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REGION IV

TECHNICAL INSPECTION BRANCH
DRAFT INSPECTION REPORT

Licensee: City of Faith Medical & Research Center
8181 South Lewis, P.O. Box 3600
Tulsa, OK 74136

Report: 8201

License: 35-19898-01

Category/Priority: G IV

Licensee Contact: Phil Prosser, Asst. Administrator
John Q. Knochel, M.D., RSO
Inspection At: Tulsa, Oklahoma

Telephone No.: 918-493-1000

Previous Inspection Dates: N/A

Findings: N/A

Current Inspection Dates: March 15 & 16, 1982

Type Inspection: Initial
unannounced

Inspection Findings

- ☐ No violations, clear 591 issued
☒ Violations, Appendix A or equivalent attached
☐ Violations, 591 issued
☒ Regional Office Letter
☐ Action on Previous inspection findings, Appendix B attached

Recommendations

- ☐ Change category to: _____
☐ Change Priority to: _____
☒ Change next inspection Date to: March 1985
☒ Inspectors comments/supplemental information, Appendix C

Persons Contacted

Bill Luttrell, Chief Adm. Officer

John Q. Knochel, M.D., RSO

Phil Prosser, Asst. Adm.

Carol Bose, Chief of Security

David Leech, Chief N.M.T.

Dan Simmons, Director of Envr. Ser.

Chris Crandall, N.M.T.

Margret Kennedy, Coordinator of

Administrative Functions for Nursing

Inspector: Jack E. Whitten, Radiation Specialist & C. A. Hooker, Rad. Spec.

Approved: [Signature]

AREAS INSPECTED AND FINDINGS

Licensee: City of Faith Med & Res Ctr License no: 35-19898-01 Amendment no:

INSPECTION ITEMS	CRITERIA	FINDING
<u>1. Organization</u>		<u>ok</u>
Structure of organization as described in requirements?	Lic Cond <u>17</u>	Per Application
Radioisotope Committee		
(a) documented meeting minutes? Yes		
(b) Meetings quarterly? Yes		Radioisotope Committee
NOTES & REMARKS:		
Phil Prosser, J.Q. Knochel, M.D., Margret Kennedy, R.N. David Leech, Chief N.M.T.		
<u>2. Licensee internal audits</u>	Lic Cond <u>17</u>	<u>Violation</u>
Scope and frequency of audits as required?	No	
Conducted by appropriate persons? Records maintained? Reviewed by management?	No	
Deficiencies identified & corrected?	No	
ALARA program? Outlined in application but not followed.		
NOTES & REMARKS:		
All applicable audits required are ALARA. Quarterly report not available of personnel exposures.		
<u>3. Training and qualification of personnel</u>	Lic Cond <u>17</u>	<u>Violation</u>
Training & retraining conducted as required?	No	
Written & oral exams conducted? Examination results reviewed by management?	N/A	
Instructions to workers per 19.12? No	19.12	N.M.Tech. not aware of having been trained in this area.
Refresher Training? N/A		
NOTES & REMARKS:		
Interviews conducted by the inspectors illustrate the lack of training and required instruction of 10 CRF 19.12 for Nursing and Housekeeping.		
<u>4. Radiation protection procedures</u>	Lic Cond <u>17</u>	<u>ok</u>
Procedures available and implemented? Identify radiopharmaceutical and dose(s)? Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?		
Emergency procedures for spills, etc? Personnel understand procedures?		
NOTES & REMARKS:		
Radiation protection procedures and Emergency procedures are available but not widely circulated. Questionable as to personnel understanding.		

AREAS INSPECTED AND FINDINGS

Licensee: City of Faith Med & Res Ctr License no: 35-19898-01 Amendment no:

INSPECTION ITEM	CRITERIA	FINDING
5. <u>Use of materials</u>	Lic Cond <u>6-8</u>	<u>Violation</u>
Procurement and use as required?	Unit dose from supplier	
Special tests (moly breakthrough, leak tests, etc) required?	N/A	
Dose calibration checks performed?	No See item 24	
Posting & labeling as required?	No 20.203, 20.204(b)	Nuclear Medicine
Approved radiopharmaceuticals?	Yes 35.14(b)	Hot Lab not posted with CRM signs.
Possession limits?	Unit dose Sr-90 Eye Applicator	
NOTES & REMARKS:	** See inspectors notes	
6. <u>Storage of materials</u>		<u>Violation</u>
Material secured in both restricted and unrestricted areas? Adequately?	No 20.207	No locks on the temporary N.M. hot lab.
NOTES & REMARKS:		No direct control of area.
7. <u>Facilities</u>	Lic Cond <u>17</u>	<u>Violation</u>
As described in lic cond or application?	No	No locks on scanning rooms in which Xe-133 is used.
Any changes made? Adequacy?		
NOTES & REMARKS:		Ventilation system not as described in application.
Approximately 6 Xe-133 scans done since issue of license.		
8. <u>Instruments</u>	Lic Cond <u>17</u>	<u>ok</u>
Survey meters & instruments adequate for program?	Yes	
Instruments & meters operable? Calibrated?	Yes	
Calibration adequate? Every 12 months?		
2 point calibration?		
NOTES & REMARKS:		
Ludlum Model 14 C with PR-2048 probe s/n 17253		Calibrated 8/3/81
Victoreen Cuti Pie 740 F s/n 2027		Calibrated 4/21/81
Victoreen out being calibrated by physicist at time of inspection.		

AREAS INSPECTED AND FINDINGS

Licensee: City of Faith Med & Res Ctr License no: 35-19898-01 Amendment no:

INSPECTION ITEMS	CRITERIA	FINDING
9. <u>Receipt and transfer of material</u>		<u>Violation</u>
Written procedures for pickup, receiving, opening packages? Yes	20.205	
Survey of packages when received? (Dose rate)	20.205(c)(1) No	
Records of survey of packages?	20.401(b) No	
Transfer of materials proper? Transfer records maintained?	30.41, 30.51 Yes	
Authorized containers used? Shipping papers & package labels proper for packages on hand?	71.5 Yes	
NOTES & REMARKS:		

Unit dose from nuclear medicine supplier

10. <u>Personnel protection - external</u>		<u>Violation</u>
Personnel monitoring controls adequate? Yes	20.101, 20.202	
Exposures minimized?		
Exposure records (NRC-4 or 5) maintained? Yes	20.102(b), 20.401(a)	
Available for employee review?		
Surveys conducted? Adequate? No	20.201	Daily radiation surveys of
Records of monitoring, surveys? Yes	20.401	N.M. not made in accordance
Levels in unrestricted areas within limits? Yes	20.1, 20.105	with application.
NOTES & REMARKS:		

Radiation surveys of N.M. made at weekly intervals in conjunction with contamination surveys.

11. <u>Personnel protection - internal</u>		<u>Ok</u>
Airborne concentrations in restricted areas?	20.103	Ok
Exposures to minors?	20.104	No minors exposed
Posting of airborne radioactivity areas?	20.203(d)	N/A
Survey, monitoring adequate for airborne radioactivity, surface contamination? Records maintained?	20.201	Air monitor built in to Xe-133
	20.401	delivery system.

NOTES & REMARKS:

Xe-133 monitor on delivery system set to alarm at 2 microcuries per liter.

AREAS INSPECTED AND FINDINGS

Licensee: City of Faith Med & Res Ctr License no: 35-19898-01 Amendment no:

INSPECTION ITEM	CRITERIA	FINDING
12. <u>Effluent controls, waste disposal</u>		<u>Ok</u>
Release of effluents controlled?	20.106, 20.303	
Waste disposals controlled?	20.301, 20.303, 20.304, 20.305	
Procedures, records maintained?	20.401, Lic Cond <u> </u>	
Surveys made? Adequate? Records?	20.401	
Records of disposals	30.51(a)	
Unit dose supplied from vendor. All materials are returned to vendor for disposal.		
13. <u>Notifications and reports</u>		<u>ok</u>
To individuals. by request	19.13	
Overexposures, excessive levels & concentrations, incidents.	20.403, 20.405 None noted	
Personnel exposures and monitoring, termination reports.	20.407; 20.408 N/A	
Theft or loss of licensed material.	20.402 None	
NOTES & REMARKS:		
14. <u>Posting of notices</u>		<u>Violation</u>
Part 20, license & documents, procedures, notice of violations posted?	19.11(a) No	
NRC-3 posted?	19.11(c) No	
NOTES & REMARKS:		
15. <u>Other license conditions</u>		<u>Ok</u>
<u>Mo-99 breakthrough</u>		
(a) ≤ 1 uCi/mCi or ≤ 5 uCi/dose?		
(b) records of tests?		
(c) written procedures?		
(d) records of training?		
Unit dose. Letter from nuclear medicine vendor outlining Mo-99 breakthrough.		

AREAS INSPECTED AND FINDINGS

Licensee: City of Faith Med & Res Ctr License no: 35-19898-01 Amendment no:

INSPECTION ITEMS	CRITERIA	FINDING
16. <u>Confirmatory measurements</u>		<u>Ok</u>
Unrestricted areas? -	Ok	Hot Lab .1 mR/h
Restricted areas?	Ok	Hot Lab Storage 1.2mR/h
		Xetex 304-A s/n 4982
		Calibrated 2/23/82

17. Independent inspection effort

Extra time on all items.

18. Incidents and eventsAny incidents of misadministrations,
contamination, etc. not otherwise
covered by reports?

35.41-44 eff. 11/10/80

None reported since operation began.

AREAS INSPECTED AND FINDINGS

78710B - Medical

19. Group IIIN/A

elution of generator per manufacturers instructions?

35.14(b)(4)

Unit doses from vendor

20. Group VI

35.14(b)(5)

Leak tests if 100 uCi?

N/A

Use per label?

Quarterly inventory?

Unopened?

Source count/survey prior to dismissal?

21. Groups I, II, & III use other than specified on label

35.14(b)(6)

Chem/physical form

N/A

Route of administration

Dosage range

22. In vitro uses under 31.11?

35.14(c)

Ok23. Calibration and reference sources

35.14(d-f)

Proper types? ok

Violation

Possession limits? ok

Leak tests? No Ba-133 7/10/81

Recd 11/11/81 results given in cpm.

Use per label? ok Cs-137 6/2/81

Quarterly inventory? Not available

Co-57 6.326 millicuries as of 9/11/81 s/n CTR-658

Cs-137 266.7 microcuries 6/1/81 3189 MA

Ba-133 234.5 microcuries 7/19/81 2124MA

24. Calibration of dose calibrator?

RG 10.8

Quarterly linearity? No

Violation

Geometrical variation? No

Annual accuracy? No

Daily reference source check? Done-but not in accordance with Reg. Guide 10.8 giving a plot of data.

25. ALARA program in accordance with NRC letter of June 16, 1980?Violation

Not done in accordance with license application tie down condition referring Reg. Guide 10.8.

Appendix A

NRC FORM 700-A 1-77 IF NO DATA INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (86418) OF LICENSE NO. (BY PRODUCT) 1354218		REPORT NO.		MODULE NUMBER		VI		
	03019451		220		57871108				
			A		VIOLATION SEVERITY OF DEVIATION		SITE RELATED		
			B		1 2 3 4 5 6		A D		
			C				F D		
		D							

License Condition 17 requires that licensed activities shall be conducted in accordance with statements, representations, and procedures contained in radioactive material license application dated November 3, 1981, with Model ALARA Program. The license application contains a commitment to follow the recommendations of Regulatory Guide 10.8.

- a. Appendix D of the Regulatory Guide requires that the dose calibrator be tested initially for geometrical variation, quarterly for linearity and annually for accuracy.

Contrary to this requirement, neither geometrical variation, quarterly linearity or annual accuracy test had been done on the dose calibrator during the period November 9, 1981 to March 15, 1982.

- b. Appendix D of the Regulatory Guide requires that the dose calibrator be tested daily for instrument constancy and the results of these daily checks be plotted on a graph as specified in Section 2.C.5.

Contrary to this requirement, daily instrument constancy checks had not been plotted on a graph during the period November 9, 1981 to March 15, 1982.

- c. Appendix I of the Regulatory Guide requires that all elution, preparation, and injection areas will be surveyed daily and decontaminated if required.

Contrary to this requirement, daily surveys of elution, preparation, and injection areas had been made weekly during the period November 9, 1981 to March 15, 1982.

- d. Appendix F of the Regulatory Guide requires that all packages containing radioactive material will have the exposure rate taken at contact and at three feet from the package.

Contrary to this requirement, the exposure rate had not been taken at contact and at three feet of any packages containing radioactive material during the period November 9, 1981 to March 15, 1982.

- e. Appendix O of the Regulatory Guide requires that the radiation safety officer make a quarterly review of occupational exposures to determine that the exposures are ALARA in accordance with Section 6 of this appendix.

Contrary to this requirement, the radiation safety officer stated that he had not made any quarterly reviews of occupational exposures as required by Appendix O during the period November 9, 1981 to March 15, 1982.

Appendix A

NRC FORM 700-A 11-81 10-11-81 INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. 1860-18 OF LICENSE NO. 1860-18 BY PRODUCT 130018										REPORT		MODULE NUMBER							
											NO.	SEQ.							VI	
												A	VIOLATION SEVERITY OR DEVIATION						SITE RELATED	
												B	1	2	3	4	5	6	A C	
												C							B D	
											D									

- f. Application section entitled "Facility Diagram" requires, in part, that the nuclear medicine "hot lab" and the Xe-133 delivery rooms have lockable doors.

Contrary to this requirement, NRC inspectors observed that neither the nuclear medicine "hot lab" or the Xe-133 delivery rooms had lockable doors on March 15, 1982.

This is a Severity Level IV violation (Supplement VI.D.2).

Appendix A

NRC FORM 700 A (Rev. 11-81) (E-MC 053) INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (E-Sign of License) NO. (BY PRODUCT) (13-9-18)										REPORT		MODULE NUMBER						VI	
											NO	SEQ								
	05019141										5201	A	VIOLATION SEVERITY OR DEVIATION						SITE	
												B	1 2 3 4 5 6						RELATED	
												C							A.C.	
											D	<div style="display: flex; justify-content: space-around;"> ✓ </div>						B.D.		
												27						2		

10 CFR 19.11(a) and (b) require that each licensee shall post current copies of 10 CFR Part 19, 10 CFR Part 20, and the license or a notice specifying where such documents may be found and examined.

Contrary to this requirement, neither the required documents nor a notice were posted on March 15, 1982.

This is a Severity Level V violation (Supplement VI.E).

Appendix A

NRC FORM 700-A 11-81 (E-M) (50) INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (BY DATE OF LICENSE)										REPORT		MODULE NUMBER						VI	
	NO. (BY PRODUCT)										NO.	SEQ.	571271103							
	05011111										8201	A	VIOLATION SEVERITY OR DEVIATION						SITE RELATED	
												B	1 2 3 4 5 6						A C	
												C							F D	
											D									

10 CFR 19.11(c) requires that Form NRC-3, "Notice to Employees," shall be posted by each licensee wherever individuals work in or frequent any portion of a restricted area.

Contrary to this requirement, such a form was not posted on March 15, 1982.

This is a Severity Level V violation (Supplement VI.E).

Appendix A

NRC FORM 700-A (Rev. 10-1-80) INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (80018) OR LICENSE NO. (BY PRODUCT) (130018)										REPORT		MODULE NUMBER						VI	
	0201P491										NC	SEC	975711018							
												A	VIOLATION SEVERITY OF DEVIATION						SITE RELATED	
												B	1	2	3	4	5	6		A C
												C								B D
											D									

10 CFR 20.203(e) requires, in part, that each area or room in which licensed radioactive material is used or stored and which contains any radioactive material in amounts exceeding 10 times the quantities specified in Appendix C of this Part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: "CAUTION RADIOACTIVE MATERIAL" .

Contrary to this requirement, NRC inspectors observed that "CAUTION RADIOACTIVE MATERIAL" signs were not posted on the doors to the nuclear medicine hot lab which contained quantities of radioactive material in excess of the amounts outlined in Appendix C of Part 20 on March 15, 1982.

This is a Severity Level V violation (Supplement VI.E).

NRC FORM 706-A (Rev. 11-81) (11-81) INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (8 digits) OR LICENSE NO. (8 digits) PRODUCT (13 digits)										REPORT		MODULE NUMBER							
											NO	SEQ	578711618 VI							
	080194511										5201	A	VIOLATION SEVERITY OF DEVIATION						SITE RELATED	
												B	1 2 3 4 5 6						A C	
												C							F D	
											D	27						2		

10 CFR 35.14(e)(2) requires, in part, that the results of leak test made of calibration or reference sources containing 100 microcuries or more of radioactive byproduct material be given in units of microcuries.

Contrary to this requirement, results of leak test made on a 234 microcurie Ba-133 and 266 microcurie Cs-137 sealed calibration sources were given in counts-per-minute on the November 11, 1981, leak test report.

This is a Severity Level V violation (Supplement VI.E).

Appendix A

NRC FORM 700-A (11-81) IF MC 050 INSPECTOR'S REPORT (Continuation) Office of Inspection and Enforcement	DOCKET NO. (8 digit) OR LICENSE NO. (BY PRODUCT) (13 digit)										REPORT		MODULE NUMBER							
	000 94911										NO		SEC		6261 VI					
											A		B		VIOLATION SEVERITY OR DEVIATION					
											B		C		1 2 3 4 5 6					
											C		D		27					
										D				SITE RELATED A C B D						

10 CFR 35.14(f)(2) requires, in part, that the licensee conduct a quarterly physical inventory to account for all sealed sources received and possessed.

Contrary to this requirement, a licensee representative stated that a quarterly physical inventory of sealed sources had not been conducted during the period November 11, 1981 to March 15, 1982.

This is a Severity Level V violation (Supplement VI.E).

APPENDIX C - SUPPLEMENTARY INFO

Licensee: City of Faith Med & Res CtrLicense no: 35-19898-01

-
- | | |
|---|--|
| <input type="checkbox"/> Uncorrected/repeated noncompliance | <input type="checkbox"/> Unresolved items |
| <input type="checkbox"/> Unusual occurrence, conditions, etc | <input checked="" type="checkbox"/> Inspector's comments |
| <input type="checkbox"/> Basis for change of Category or Priority | |

The unauthorized Sr-90 applicator problem was followed to verify that the material was received as stated, placed in storage immediately as stated, and not used since that receipt date. According to the information provided by the licensee and visual observation by the inspectors all is in compliance. They are currently in receipt of their ammendment to possess said material.

It is the strong belief of these inspectors that more stringent administration of the nuclear medicine and/or radiation safety program is required. This is most obvious when looking at the radiation safety officers lack of understanding of the radiation safety program.

Seeing as a broad license is just around the corner for ORU and City of Faith, careful consideration should be given to examining both these programs before the issuance of such a license. We would suggest that City of Faith be reinspected in six to nine months from the date of this inspection.