NRC Form 591
(12-84)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

DMB COPY

1. LICENSEE	2. REGIONAL OFFICE
Syncor International Corp. (Diagnostic Management Inc.) 2233 University Avenue Suite 220 St. Paul, MN 55114	U.S. NUCLEAR REGULATORY COMMISSION REGION III 799 ROOSEVELT ROAD GLEN ELLYN, ILLINOIS 60137

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
030 - 17084	22 - 19174 - 01MD	July 18, 1985

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

[ ] 1. Within the scope of this inspection, no violations were observed.

[X] 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

[X] 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements.
THIS IS A NOTICE OF VIOLATION which is required to be posted in accordance with 10 CFR 19.11.

[ ] A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (c), (d), (e) or 34.42.

[ ] B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

[ ] C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

[X] D. Records of dose calibrator geometry tests were not properly maintained. ~~10 CFR~~ _____ or License Condition Number 22.

[ ] E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

[ ] F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

[X] H. Records of vehicle contamination surveys performed on delivery automobiles were not adequately maintained. License condition No. 22

[ ] I. _____

[ ] J. _____

[ ] K. 8508070524 850718
REG3 LIC30
22-19174-01MD PDR

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE – LICENSEE	DATE	SIGNATURE – NRC INSPECTOR	DATE
David Zielkowski RPh	7/15/85	James L Lynch	7/18/85

IE07 0/1

NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

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License File

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[X] D. Records of dose calibrator geometry tests ~~[illegible]~~ were not properly maintained. ~~[illegible]~~ or License Condition Number 22.

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SIGNATURE – LICENSEE	DATE	SIGNATURE – NRC INSPECTOR	DATE
David Zidkowski RPh	7/16/85	James L Lynch	7/18/85

DRAFT
Module No. 78710B

REGION III

NUCLEAR MATERIALS SAFETY SECTION

MEDICAL INSPECTION REPORT

Inspection Report No. 85001

Licensee (Name and address)

Diagnostic Management Inc. (Syncor Corp.)

2233 University Avenue
Suite 220
St. Paul, MN 55114

Licensee Contact: David Ziolkowski Telephone No. (612) 645-3000

License No. 22-19174-01 MD Docket No. 030-17084

Last Amendment No. 06 Date of Amendment: 12/30/83

✓ Category: G1 Priority: II

Date of Inspection: July 18, 1985

Type of Inspection: ( ) Announced (✓) Unannounced (✓) Normal
( ) Initial ( ) Special (✓) Reinspection

Next Inspection: 0787 ( ) Reduced ( ) Extended

Program Codes: ( ) 02110 - Broad ( ) 02120 - Group ( ) 02121 - Non-Group
( ) 02200 - Pv.Prac. ( ) 02210 - Eye App.
( ) 02201
( ) 02220 - VAN (✓) 02500 - Pharmacy ( ) Other

Summary of Findings and Action:

( ) No Noncompliance, Clear 591 issued ( ) Action on Previous N/
(✓) Noncompliance, 591 issued ( ) Regional Action
( ) Noncompliance, Appendix A ( ) Hq Action

Inspector James L Lynch (Signature) 7/25/85 (Date Signed)

Approved J. D. Hinds (Signature) 7/25/85 (Date Signed)

Rev. 08/01/84

1. INSPECTION HISTORY

a. Item(s) of noncompliance or deviations noted during last inspection conducted on: 11/29/83 (✓) Yes ( ) No. Reponse letter dtd 591

b.

		Corrective Action Taken		Status	
Requirement	Type of N/C	(✓) Yes	( ) No	Open	Closed
✓ Leak tests					
inoperable survey instrument					

c. If any item(s) of noncompliance or deviations noted during last inspection were not corrected, explain:

2. ORGANIZATION

a. Administrative structure meets License requirements: (✓) Yes ( ) No [L/C]

Frank Comer - Corporate RSO
✓* David Ziolkowski, RPh - RSO, Manager
Steve Piepenbrink, RPh - Asst Manager
John Flack, RPh

* Attended Management close-out meeting

b. Use by authorized individuals: (✓) Yes ( ) No

[L/C]

One individual listed on Syncor's master license (34-16654-01MD) must be physically present when material is used. Ziolkowski, Piepenbrink & Flack are on the license. One of these three are in the pharmacy whenever material is used. (CONT 1219)

c. Isotope Committee meets at required intervals: ( ) Yes ( ) No

[L/C]

N/A

d. Record of Committee meetings: ( ) Yes ( ) No

[L/C]

N/A

3. SUMMARY OF PROGRAM

DMI (now known as Syncor) provides nuclear pharmacy services for the Twin Cities area. 26 client hospitals and about 25 other businesses (labs, physicians, etc) are served at present. ≈ 3300 doses are prepared monthly.

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by License Condition: ( ) Yes (✓) No

b. Audits or Inspections conducted: (✓) Yes ( ) No

[L/C]

Quarterly audit by Syncor health physicist

c. Records maintained: (✓) Yes ( ) No

[L/C]

5. TRAINING, RETRAINING AND INSTRUCTION TO WORKERS

a. Training program required by License Condition: (✓) Yes ( ) No

b. Training program implemented: (✓) Yes ( ) No

[L/C]

Inservice

c. Retraining program required by License Condition: (✓) Yes ( ) No

d. Retraining program implemented: (✓) Yes ( ) No

[L/C]

Annual retraining

e. Instruction to workers in accord with 10 CFR 19.12: (✓) Yes ( ) No

[19.12]

✓ I instructed the RSO to review procedures with staff at Pet Cremations, where decayed waste is taken to be incinerated. They need to be informed of importance of insuring that labelled vials & syringes are promptly incinerated.

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Procedure referenced in License Condition: (✓) Yes ( ) No

b. Use in accordance with referenced procedure: (✓) Yes ( ) No

[L/C]

Syringes labeled prior to filling
Syringe & vial shields used.

c. Individual's understanding of procedures adequate: (✓) Yes ( ) No

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in License Application: (✓) Yes ( ) No

[L/C]

✓ 2233 University (Wright Bldg). Since a ~~new~~ receptionist is no longer employed, enter the facility via loading dock.

b. Isotope, chemical form, quantity and use as authorized: (✓) Yes ( ) No

[L/C]

✓ The licensee distributes sealed sources (calibration) used generators, iodine doses, xenon unit doses & P-32 doses, as well as other radiopharmaceuticals.

c. Tests required by License Condition or Regulations

(1) Molybdenum-99 breakthrough: (✓) Yes ( ) No

(2) Performed as required: (✓) Yes ( ) No

[L/C and/or 35.14(b)(4)iii]

Each elution

✓ Alumina breakthough also performed.

(3) Leak tests: (✓) Yes ( ) No

(4) Leak tests performed as required: (✓) Yes ( ) No

[L/C] [35.14(b)(5)(i) or 35.14(e)(1)(i)]

✓ semiannually. Performed on in house standards and other sources ready for distribution if outside 6 month limits. About 3 sealed sources sold monthly.

(5) Other tests required:

d. Inventory of sealed sources

(1) Inventory of Group VI sources: ( ) Yes ( ) No

[35.14(b)(5)(v)]

N/A

(2) Inventory of calibration sources: (✓) Yes ( ) No

[35.14(f)(2)]

computerized inventory.

e. Storage of radioactive materials

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate: (✓) Yes ( ) No

✓ Delivery courier places material through a small door which leads to a locked box in pharmacy.

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area: (✓) Yes ( ) No

[20.207] locked materials secured in rear trunks with straps.

f. Instrumentation

(1) Operable survey instruments as described or equivalent to those described in License Application: (✓) Yes ( ) No

[L/C]

Ludlum 5, 14C, 177

(2) Capability of radiation survey instruments adequate for program

(✓) Yes ( ) No

✓ Surv. y instrument carried in each vehicle

(3) Calibration of survey instruments required: (✓) Yes ( ) No

(4) Performed as required: (✓) Yes ( ) No

[L/C]

Annually by Syncor-Kansas City

(5) Dose calibrator checks required: (✓) Yes ( ) No

(6) Performed as required: (✓) Yes ( ) No

[L/C]

✓ Daily constancy performed but not always prior to assaying morning doses. RSO stated that a constancy test will be performed prior to any doses being prepared in the future. (CONT #19)

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Survey of incoming packages: (✓) Yes ( ) No

[20.205(b)(1) or L/C]

All cases are wipe tested before deliveries are made.

b. Record of survey: (✓) Yes ( ) No

[20.401(b)]

c. Procedure for opening packages: (✓) Yes ( ) No

[20.205(d)]

✓ Survey at 3 ft & surface, wipe test (analyze with GM)

d. BPM transferred in accordance with 10 CFR 30.41: (✓) Yes ( ) No

[30.41]

✓ Customer licenses on file and in computer. The current computer program needs revision in that,

e. Records of receipt and transfer maintained: (✓) Yes ( ) No

[30.51]

the computer allows distribution of all isotopes in a Group even though the customer may not be licensed to possess all of those isotopes. For example, a hospital authorized for I-131 hyperthyroidism would be allowed to receive P-32 also because it is part of Group II even though its not authorized. The RSO stated that he would have the program updated.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD badge supplier: Landauer Frequency: Monthly *

b. Reports reviewed by: Manager Frequency: Monthly *

c. NRC inspector reviewed personnel monitoring records for period 1/83 to 6/85

* Individuals drawing doses wear weekly TLD rings

d. NRC forms or equivalent

(1) NRC-4: ( ) Yes (✓) No Complete: ( ) Yes ( ) No

(2) NRC-5: (✓) Yes ( ) No Complete: (✓) Yes ( ) No

[20.401(a)]

✓ No overexposures according to RSO

e. Maximum ~~quarterly~~ annual whole body exposure: 150 mrem

f. Maximum ~~quarterly~~ annual extremity exposure: 19930 mrem

g. Licensee has implemented the ALARA program: (✓) Yes ( ) No

h. Radiation survey of unrestricted area: ( ) Yes (✓) No

[20.201(b) to show compliance with 20.105(b)]

✓ LC 22 (12/26/79 letter) states that all delivery vehicles will be surveyed daily. The individual in charge

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i. Record of survey maintained: ( ) Yes ( ) No (CONT #19)

[20.401(b)]

One survey record used for all vehicle surveys at present

j. Radiation survey of use areas (hot lab, therapy treatment area, patient's room, etc.): (✓) Yes ( ) No

[L/C]

Daily survey & wipe of use areas ≈ 30 positions.

k. Record of survey maintained: (✓) Yes ( ) No

[L/C]

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10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists: (✓) Yes ( ) No

b. Monitoring for airborne radioactivity conducted: ( ) Yes (✓) No

[20.201(b) to show compliance with all sections of 20.103 or L/C]

✓ Xe-133 and I-131 liquid received in unit doses from manufacturers. Seals are not broken but vials kept in hood. Hood velocity & airflow is checked semiannually.

c. Records of monitoring maintained: (✓) Yes ( ) No

[20.401(b) or L/C]

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11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas: ( ) Yes (✓) No

b. Release in accordance with regulatory limits: (✓) Yes ( ) No

[20.106(a)]

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c. Solid waste disposal method: Generators to manufacturers
Other waste segregated by half life and decayed.

d. Liquid waste disposal method: Same.

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage): (✓) Yes ( ) No

f. Records of disposal: (✓) Yes ( ) No
[30.51]

g. Survey of waste prior to disposal: (✓) Yes ( ) No
[20.201(b) to show compliance with 20.301]
Only decayed (surveyed) waste goes to Pet Cremations for incineration.

h. Records of surveys maintained: (✓) Yes ( ) No
[20.401(b)]

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (Reports to individuals)

(✓) Yes ( ) No [19.13]

b. Licensee in compliance with 10 CFR 20.405 (Over exposures)

(✓) Yes ( ) No [20.405(a)]

c. Licensee in compliance with 10 CFR 20.403 (Incidents)

(✓) Yes ( ) No [20.403]

✓ 9/25/84 vehicle accident reviewed - no problem with isotopes.

d. Licensee in compliance with 10 CFR 20.402 (Theft or loss)

(✓) Yes ( ) No [20.402(a) or 20.402(b)]

e. Licensee in compliance with 10 CFR 35.42 or 10 CFR 35.43 (Misadm.)

(✓) Yes ( ) No [35.42 or 35.43]

✓ 3 misadministrations occurred in 1984, all where due to pharmacist errors. Color coding of vials, separation of similar kits and stricter procedures have been enacted.

13. POSTING OF NOTICES

Notices to workers posted: (✓) Yes ( ) No

[19.11(a) or (b) 19.11(c)]

14. CONFIRMATORY MEASUREMENTS

a. Independent measurements made by inspector: (✓) Yes ( ) No

b. Survey Instrument: Xetex-305B NRC Ser. No. 9006

Last date of calibration: 7/8/85

c. Describe type and results of measurements and compare with licensee's measurements: Survey, hot lab < 1.0 mR/hr storage < 1.5 mR/hr, garage (not Syncor's) opposite generator room < 0.3 mR/hr, outside walls < 0.2 mR/hr.

✓

15. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203: (✓) Yes ( ) No

[20.203]

✓ Cases have correct transport labels
T.I. is calculated prior to transport
Cases are covered upon return to Syncor.

16. LICENSE CONDITIONS

a. All License Conditions reviewed during inspection: ( ) Yes ( ) No

b. Activities were conducted in accordance with License Conditions except as noted elsewhere in this report: ( ) Yes ( ) No

17. BULLETINS AND CIRCULARS

a. Bulletins and Circulars issued during current year:

N/A

b. Bulletins and Circulars received by licensee: ( ) Yes ( ) No

c. Licensee took appropriate action in response to Bulletins and Circulars: ( ) Yes ( ) No

18. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

		Yes	N/A	Vio
a.	License makes shipments of RAM?	(✓)	( )	( )
	If no, check N/A and stop here:			
	If yes, complete the following items:			
b.	Such shipments consist of:			
	( ) Radwaste			
	(✓) Sources/products			
	( ) Other_____			
c.	For radwaste, shipments are: N/A			
	( ) by licensee, using common carrier			
	( ) through Radwaste Broker			
	name of broker _____			
d.	Licensee is aware of 10 CFR 61 Radwaste requirements for generators?	(✓)	( )	( )
	Licensee has classified and characterized his radwaste? (20.311(d))	(✓)	( )	( )

e. For shipments:

Licensee uses authorized packages? (173.415-16)	(✓)	( )	( )
Package type used: DOT 7-A			
For DOT-7A, licensee has performance test records on file? (173.415(a))	(✓)	( )	( )
For special form sources, licensee has performance test records on file for each source design? (173.476(a))	(✓)	( )	( )
Packages are properly labeled? (172.403 & 173.441)	(✓)	( )	( )
Packages are properly marked? (172.300.172.301. 172.310)	(✓)	( )	( )
Proper shipping papers are prepared for each shipment? (172.200,172.201,172.202, 172.203(d))	(✓)	( )	( )

Notes/Comments:

✓ Shipping papers are carried with shipments in delivery vehicles. Customers are encouraged to hold unused doses until activity is below limited quantities.

19. CONTINUATION OF REPORT ITEMS

2(b) Normally, two pharmacists are on duty in the morning and one in the afternoon. One of the 3 is on call during off hours. It was strongly suggested that an additional authorized user be added so that coverage will be provided when the users are ill or on vacation. One technician-driver and 7 drivers round out the staff. The authorized users (pharmacists) are the only people that prepare radiopharmaceuticals and doses.

7(f)(6) Linearity tests done quarterly, accuracy tests also quarterly (required annually). No records of geometry tests on Capintec CRC-6 and CRC-12R dose calibrators available. Lc 22 (12/26/79 letter). The RSO stated they would be done immediately

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3.D.
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9(h) of performing those surveys stated that records not maintained all vehicles are surveyed daily. It was suggested that a log be maintained in each vehicle so that it would be obvious that surveys were needed. The RSO said that this would be implemented.