syncor

December 3, 1990

Director, Office of Enforcement U.C. Nuclear Regulatory Commission Attn: Document Control Desk Washington D.C. 20555

> RE: DOCKET NO.: 030-15125 License No. 37-18461-01-MD "Reply to a Notice of Violation"

Gentlemen:

Syncor's management has made the decision to respond to your "Notice of Violation and Proposed Imposition of a Civil Penalty" by paying the civil penalty. The payment of this fine is not an admission of guilt but a desire to close this matter.

At this time I would like to clarify two statements made in your letter dated November 5, 1990. First, and I quote, "At the enforcement conference, your staff indicated that, as a result of the 1985 events, a specific training presentation was developed and provided to all employees regarding the security of licensed material in their vehicles and protection against unauthorized removal."

Dr. Mullen and Mr. Prosser, the Syncor employees attending the enforcement conference, were asked about this statement and they have denied the events of 1985 were even mentioned or discussed. The reason for my concern is that a specific training program was not developed as a result of the 1985 security violation which resulted in a \$2500 civil penalty. This program was in place prior to the violation and subsequent fine and the auditors of Syncor were already auditing for compliance in our 32 pharmacies.

As you are aware, your agencies did not identify any areas of noncompliance regarding a security violation for the next 5 years. During this time frame our company grew from 32 to 84 pharmacies.

In our continuing effort to help our field staff train new and existing personnel, we begain the development of eight new training tapes in late 1989. These tapes were distributed to the field during May of 1990. One of these training tapes covered those training requirements listed in 10 CFR, 19.12. As a part of this tape there is a section dealing with specific training for Syncor's delivery personnel or customer service assistants (CSA). This section deals with security of licensed material in their vehicles, and protection

Innovators in high-tech pharmacy services

1 W/ 12, 500 # 239308 U.S. Nuclear Regulatory Commission Att:: Document Control Desk Page 2

against unauthorized removal. This program also deals with security measures at customer sites. As you can see these tapes were completed and in the field prior to the incident in Folcroft.

This Jeads to my second area of concern and I quote, "Your corrective actions as described above, while adequate, were not considered sufficiently comprehensive to warrant mitigation, (the actions narrowly focused on the specific violation at the Folcroft facility and did not evidence an adequate level of corporate involvement, particularly in light of previous problems in Grand Rapids and Hartford, to ensure that control of radioactive material is maintained at all of your facilities) and, therefore, no adjustment to the base civil penalty of this factor is appropriate."

I am concerned the U.S. Nuclear Regulatory Commission arrived at this conclusion because Syncor management was not adequately represented at the enforcement conference. At this time I would like to explain why I believe this.

When Mr. Frank Comer, the Corporate Radiation Safety Officer, was notified by Dr. Bettenhausen of the need for an enforcement conference, Mr. Comer was concerned and expressed his concern to Dr. Bettenhausen. This concern was based on the previous security violations in 1985, and the fact the violations in Folcroft were identified by the same NRC inspector who had identified the security violation which resulted in a fine in 1985. Mr. Comer asked Dr. Bettenhausen who from the corporate office should attend this meeting. Dr. Bettenhausen indicated Region I simply wanted to discuss the violations with the local manager, and that it would not be necessary for corporate management to attend the conference. Because of this conversation with Dr. Bettenhausen, corporate management made the decision not to attend the enforcement conference.

To assume Syncor management narrowly focused on the specific violation at the Folcroft facility and did not evidence an adequate level of corporate involvement is a wrong assumption. On two occasions, Mr. Comer called and talked to Dr. Shanbaky, Chief of Nuclear Materials Safety Section A, informing him of actions being taken by Syncor to address this matter corporate-wide.

To further support my belief, I am enclosing a series documents which were generated as a result of the Folcroft inspection and subsequent enforcement conferences. The earliest document was generated by our eastern zone manager on Friday, September 7, 1990, two days after the enforcement conference. Additional information was sent to their respective pharmacies by other zone and regional managers, copies of which I have enclosed. Last but not least I have enclosed a letter which I wrote and sent to every Syncor employee at their home. While this information may not effect or mitigate the civil penalty, I want

U.S. Nuclear Regulatory Commission Attn: Document Control Desk Page 3

this information to become a part of the record which will be placed into the public document room.

The following is our "Reply to Notice of Violation":

I. VIOLATION ASSESSED A CIVIL PENALTY

10 CFR 20.297 (a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207 (b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on August 9, 1990, millicurie quantities of licensed material (specifically, Technetium-99m and Iodine 131) were placed in two motor vehicles located in the licensee's parking lot (unrestricted area) in Folcroft, Pennsylvania, and for approximately 10 minutes on that date, the materials were neither secured against unauthorized removal nor under constant surveillance and immediate control of the licensee. Specifically, both vehicles were left unlocked and unattended, and one of the vehicles had the keys in the ignition with the motor running. This is a Severity Level III violation (Supplement VI).

Civil Penalty - \$12,500.00

- 1. The violation is denied.
- 2. This violation is denied because the Syncor manager and the customer service assistants (CSA) allegedly involved in the violation have stated that another CSA was present in the parking lot. See attached employee statement.
- 3. Even though the violation is denied, Syncor recognizes the seriousness of this type of violation and has taken extensive corrective action, both at the Folcroft location and at all other Syncor locations.

The corrective actions relative to this alleged violation are:

- a. To hold a safety review with the Folcroft facility personnel focused on the need for security of unattended vehicles.
- b. To ensure implementation of Syncor's policy and the requirements of 10 CFR 20.207 (a)(b) requiring all unattended vehicles to be secured against entry or

U.S. Nuclear Regulatory Commission Attn: Document Control Desk Page 4 theft and/or under constant surveillance and immediate control of the licensee. The results are achieved by having an individual provide surveillance over all vehicles being loaded with radioactive material during the early morning runs. The corrective steps which have been taken to avoid further violations are those requiring surveillance by an individual during the early run. Full compliance was achieved on August 10, 1990. VIOLATION NOT ASSESSED A CIVIL PENALTY II. Condition 17 of License No. 37-18461-01MD, requires that licensed material be transported in accordance with the provisions of 10 CFR 71. 10 CFR 71.5(a) requires, in part, that transportation of licensed material outside of the confines of the licensee's facility or other place of use be made in accordance with the applicable requirements of the Department of Transportation in 49 CFR 170-189. 49 CFR 173.448(a) requires that each shipment of radioactive materials be secured in order to prevent shifting during normal transportation. 1. This violation is admitted. 2. This violation was by a recently hired employee who failed to comply with his training with Syncor policy, and the provisions of 49 CFR 173.448 (a) (b). It was apparant that other employees were in compliance with this regulation as attested by the NRC inspector.

3. A meeting was held with the customer service assistants

secured against movement during transport.

times during transport.

concerning securing radioactive packages in their vehicles. Individuals performing surveillance in the parking lot during package loading will also check to insure that packages are

4. To avoid further violations, all vehicles will be checked to ensure that packages are secured against shifting during transport prior to leaving the parking lot. All customer

service assistants have been directed to secure packages at all

U.S. Nuclear Regulatory Commission Attn: Document Control Desk Page 5

5. Full compliance was achieved on August 10, 1990.

In summary, we have paid the fine rather than spend our resources and energy on administrative challenges. We will focus our time and energy on improving our quality results.

Historically, we have done an excellent job of providing quality products and services to our customers. For example:

+Syncor pharmacists make one error leading to a misadministration in every 50,000 doses drawn.

+The total industry average is one error leading to a misadministration in every 8,333 doses drawn.

In a recent letter to my fellow Syncor Employees I stated the following: "While we are better than the industry average.... these results are not good enough. Our goal must be ZERO errors. This goal must be accepted by everyone in the Company....To purse this goal, we must all believe and demonstrate that Syncor is dedicated to EXCELLENCE!....Syncor is dedicated to QUALITY.....Syncor is dedicated to being recognized as an ENVIRONMENTALLY RESPONSIBLE COMPANY!"

Sincerely,

Gene McGrevin

President and C.E.O.

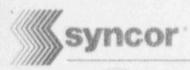
Syncor International Corporation

GM:dlo Enclosures

Enclosure:

Employee Statements Enforcement Memos

\$12,500.00 Civil Penalty check





November 14, 1990

Dear Fellow Syncor Employee:

Historically, Syncor has done an excellent job of providing quality products and services to our Radiopharmacy and Home Care customers. Our results in these highly regulated businesses speak for themselves. For example, in our Radiopharmacy business:

- Syncor pharmacies make one error leading to a misadministration in every 50,000 doses drawn.
- The total industry average is one error leading to a misadministration in every 8,333 doses drawn.

In other words, our quality is <u>better</u> than the industry average. <u>However, these results are not good enough</u>. To help you understand why we cannot be satisfied with these results, I would like to relate to you the business impact of making errors and not complying with regulations.

Recently we have received two letters of violation from the Nuclear Regulatory Commission (NRC). These violations have resulted in financial penalties. The first incident involved the preparation of "super" kits, record falsification and multiple misadministrations. While the NRC proposed a fine of \$20,000, it is currently in the appeal process.

The second incident occurred in one of our pharmacies in NRC Region I and it has resulted in a civil penalty of \$12,500. The NRC inspector identified two separate security violations. In each instance the Customer Service Assistants were in our parking lot and left their vehicle containing radioactive material unattended and unlocked.

This is the third time within the last five years the NRC has identified this problem at a Syncor facility and it is the second time we have received a fine. I have been told by members of the Quality and Regulatory Group future violations in this area could lead to a Severity Level II violation resulting in fines of six figures and additional operating penalties.

Last week I received a call from the NRC stating I would be faxed the press release of the latest incident. This press release will be sent to the various news media. Unfortunately, these isolated incidents are the ones that get press



September 4, 1990

When Syncor employee Christine Benko left her loaded car in the parking lot, there were 2 other Syncor employees present in the area. The drivers understood that the loaded vehicle was not unattended since at least one other employee was present in the area. The driver does not recall being questioned by the inspector prior to entering the building.

DATE: 9-4/90 Christine Bento

Syncor Employee Signature

CHRISTINE BENKO

syncor'

September 4, 1990

When Syncor employee Bill Bennett left his loaded vehicle in the parking lot there were other Syncor employees in the parking lot. Mr. Bennett understood that if another Syncor employee was present in the area, the car was not unattended. He also does not recall being away from his car for ten minutes. This occurred during the inspection of 8/9/90.

DATE:

Syncor Employee Signature

William Bennet

BILL BENNETT

Date: Mon, 24 Sep 1990 11:09 edt Via: 1 Via: 1 To: loc 03 To: loc 04 To: 100 06 To: 100 07 To: loc 13 To: loc 18 To: loc 19 To: 100 24 To: 100 26 To: 100 29 To: loc 34 To: loc 71 To: 100 72 To: 100 73 To: 10c 80 To: loc 88 To: Brian Bender To: Rodney Prosser To: Peter van der Wal To: Jeff Dzieweczynski To: Joe Fery Subject: (Forwarded) REGULATORY UPDATE Cc: Syncor EMS: Syncor mbx: Jack Coffey

THIS MEMO IS TO BE CONSIDERED A WRITTEN WARNING TO ANYONE WHO LEAVES A VEHICLE UNSECURED. THAT INDIVIDUAL WILL BE TERMINATED IF THIS CONDITION OCCUR3. THE VEHICLE MUST BE LOCKED AT ALL TIMES THAT THE DRIVER OF THAT VEHICLE IS NOT EITHER IN THE VEHICLE OR WITHIN ONE ARM'S LENGTH OF THAT VEHICLE. THE VEHICLE DOES NOT HAVE TO CONTAIN RADIOACTIVE MATERIAL FOR THE TERMINATION TO OCCUR.

ALL EMPLOYEES IN THE EASTERN ZONE ARE TO SIGN AND DATE THIS MEMO. IT IS TO BE RETURNED TO YOUR REGIONAL MANAGER BY 10/5/90.

YOUR COMPLIANCE WITH THE ABOVE IS APPRECIATED.

THANK YOU.

GARY REDMORE, ZONE DIRECTOR

Forwarded message

Date: Fri, 7 Sep 1990 10:50 edt

Via: 1 Via: 1 To: loc 03 To: loc 04 To: loc 06 To: loc 07 To: loc 13 To: loc 18

To: loc 19

To: 100 24 To: 100 26 To: 100 29 To: 100 34 To: loc 71 To: loc 72 To: loc 73 To: 100 80 To: loc 88 To: Rodney Prosser To: Peter van der Wal To: Jeff Dzieweczynski To: Joe Fery Subject: REGULATORY UPDATE Cc: Syncor EMS: Syncor mbx: Jack Coffey TO: EASTERN ZONE MANAGERS RODNEY PROSSER FROM: GARY REDMORE 9/8/90 DATE: RE: REGULATORY ITEMS On Wednesday, Rodney Prosser spent the morning with the NRC discussing recent regulatory violations that may have occurred in NRC Region One. The NRC was very concerned about the blocking, bracing, and security of our packages. In addition to this, we received a violation for not completing the training as stated in our license application. By next week I would like each location to evaluate these items and comply with the following. 1. Every authorized user is to read the license application(3) by the end of October 1990. We are bound to this application. It is impossible for authorized users to comply, if they do not know what is in the application. All new authorized users are to read the license application(s) during their first four weeks of employment. Each authorized user is to read both State and NRC license applications on an annual basis. This is to be documented on the RS-59 form. Every manager is to evaluate blocking, bracing and security of the radioactive packages. Three years ago, we received a violation for this in Region One and it resulted in a \$10,000 fine. At this point, I do not know what the NRC will implement as a result of the most recent violation. During your audits, I would like you to emphasize this area. Do spot inspections on your drivers. These inspections should be unannounced. They can be accomplished by waiting for your driver at the Nuclear Medicine Departments and escorting them to the parking lot. Make sure the delivery personnel are complying with the following: 1. The vehicle is locked. Case covers or flip cards are being used.

. . 3. . All packages including returns are secured.

I realize, that locations secure the packages in different ways. You should have an accepted method for your location and it should be followed. If you use cables in one car, then you should use cables in all cars.

It is important that the delivery personnel recognize the seriousness of a repeat violation in Region One. The next violation will cost us thousands of dollars. In addition to the fine, the cost of corrective action could be astronomical. How would you like to send two drivers on every run (one to drive and the second to verify the fact that the driver locked his car.)

Last of all, make sure that all drivers know that if they fail to secure their packages it could result in termination. The bottom line is that we can not afford another violation in this area.

I wish to thank Rodney for being concerned enough to provide the direction shown in this memo.

Have all employees sign this memo and return it to your Regional Manager.

End forwarded message

End forwarded message

Message. Dated: 11/13/90 at 1144.

Subject: Security Violations

Sender: Paul SALE / MCI/GW Contents: 3.

Part 1.

TO: Frank COMER / SYNCOR/00

Part 2.

MESSAGE HEADER.

Part 3.

Frank,
Here is the information that I had distributed to my region following a
thorough discussion of the issue at my regional meeting the first week of
October. You are already in receipt of a memo Joe Huber (St. Louis) wrote
to his employees as a follow-up to this.
-Paul

Forwarded message

Date: Wed, 17 Oct 1990 20:05 cst

Via: 1

To: Loc 10

To: Loc 15

To: Loc 16

To: Loc 30

To: Loc 33

To: Loc 36

To: Loc 64

To: Loc 70

Subject: Security Violations

Cc: Curt Blaum

At our regional meeting we discussed the recent problem of security violations at several locations. As a follow-up to that discussion I am forwarding the memo from Jack and Richard addressing this issue since some of you may not have received it earlier.

This topic needs to be discussed with all employees as future violations will not be treated lightly by company auditors or other regulatory agencies. Remember that a violation in this area during a company audit will automatically put your location into the "below standards" ranking regardless of any other findings during the audit.

Thanks for your attention to this matter.

-Paul

TO: All NRC Locations, Regional and Zones

FROM: Jack Coffey Richard Keesee SUBJECT: Security Violation in NRC Pharmacies

DATE: September 26, 1990

We have a potentially serious problem developing in our Nuclear Regulatory Commission (NRC) pharmacies. This problem relates to drivers placing radioactive material in UNLOCKED/UNATTENDED cars and then returning to the pharmacy.

Auditors from both the NRC and the Syncor Quality and Regulatory Department have recently issued violations for this infraction. This is serious and if not corrected immediately will lead to escalated enforcement by the NRC. Penalties usually associated with escalated enforcement include fines and /or modifying orders.

This violation can be prevented by:

- requiring the drivers to lock their unattended cars when returning to the pharmacy for additional cases.
- place an individual in the parking lot to maintain constant surveillance of the unattended automobiles.

Please take appropriate measures to prevent occurrence and/or reoccurrence.

Thank you,

Jack and Richard.

End forwarded message

COMER, FRANK / SYNCOR/00 - HPDesk print.

Dated: 11/09/90 at 0823. Message.

LOCKING OF VEHICLES Subject:

Sender: Joe ZIPP / MCI/GW Contents: 3.

TO: Frank COMER / SYNCOR/00

Part 1.

TO: Frank COMER / SYNCOR/00 Richard KEESEE / SYNCOR/00

Part 2.

MESSAGE HEADER.

Part 3.

I knew there was another memo.... I misfiled it! This one went out October 7, 1990. Hope this will help.

Thanks, Joe

Forwarded message

Date: Sun, 7 Oct 1990 8:27 cst

Via: 1 Via: 1

To: Dennis Blair

To: Loc 17

To: Loc 28

To: Loc 37

To: Loc 38

To: Loc 39

To: Loc 47
To: Loc 48
To: Loc 63
To: Wade Hopkins

To: Loc 49

To: Loc 50

To: Loc 54

To: Loc 55

To: Loc 56

To: Loc 57 To: Loc 61

To: Loc 62

To: Loc 81

Subject: LOCKING OF VEHICLES

Managers,

Please be aware that we are in deep trouble with the regulatory agencies about leaving our delivery vehicles unlocked and unmanned while they contain RAM shipments. Please be forewarned that any internal audit finding a vehicle unlocked will immediately drop your pharmacy out of the satisfactory category. Again please remember that bonus payout is directly related to your location's regulatory performance.

Therefore, please meet with your staff and document that meeting as an in-service, with signatures of all personnel attending and file that document.

This meeting format will be to inform total staff that the delivery vehicle will be locked AT ALL TIMES regardless of RAM aboard or not. If we train ourselves to lock the vehicle every time we leave it, I feel it will become second nature to do so, rather than trying to remember to lock it when loaded with RAM and not locking it if not loaded. This may be a bit of an over kill, but with everyone having the direction TO KEEP THE VEHICLE LOCKED AT ALL TIMES, we should be under immediate compliance in this area.

Please remember as manager, it is your responsibility to monitor and assure compliance in the area.

Thanks, Joe

End forwarded message

COMER, FRANK / SYNCOR/00 - HPDesk print.

Message.

Dated: 11/08/90 at 1008.

Subject:

Sender: Joe ZIPP / MCI/GW

TO: Frank COMER / SYNCOR/00

Contents: 3.

Part 1.

TO: Frank COMER / SYNCOR/00 Richard KEESEE / SYNCOR/00

Part 2.

MESSAGE HEADER.

Part 3.

Gentlemen,

Attached is the directive I sent to the Central Zone Managers, October 16, 1990, requesting an IMMEDIATE audit of their pharmacy with emphasis placed in five categories. Please note category #4 was to focus on security violations in two areas ... The automobile and the facility.

Thanks, Joe

Forwarded message

Date: Tue, 16 Oct 1990 13:04 cst

Via: 1

Subject: (Forwarded)

Via: 1

To: Dennis Blair

To: Loc 17 To: Loc 28

To: Loc 37 To: Loc 38

To: Loc 39

To: Loc 47

To: Loc 48

To: Loc 63

To: Wade Hopkins

To: Loc 49 To: Loc 50

To: Loc 54
To: Loc 55
To: Loc 56
To: Loc 57

To: Loc 61

To: Loc 62

To: Loc 81

Forwarded message

Message-Id: 62901018204926/0003327225NB3EM Source-Msg-Id: 6776143 0 0 0 "MCI GW"&Verne TABACON Managers, Please do an immediate audit of your regulatory program's compliance in the following areas. Please correct any problems with a note to file.. "Internal audit discovered the following area of noncompliance This area of noncompliance corrected as of (date)" Thanks, Joe 1. Interim Final Rule - audit compliance in all NRC Pharmacies 2. Internal/External Exposure Weekly Ring Badges - RS-15/17 b. Bioassy Air Monitoring C. RSO follow up of exposures exceeding corporate ALARA MRSPL 3. 1. possession limits 2. documentation of timely renewal of customer licenses 4. Radioactive Material security violations in the 1. automobile 2. facility 5. Driver compliance End forwarded message End forwarded message

COMER, IRANK / SYNCOR/00 - HPDesk print.

Message.

Subject: Locking Vehicles

Sender: Joe ZIPP / MCI/GW TO: Frank COMER / SYNCOR/00

Dated: 11/09/90 at 0825.

Contents: 4.

Part 1.

TO: Jack COFFEY / SYNCOR/00 Frank COMER / SYNCOR/00 Richard KEESEE / SYNCOR/00

Part 2.

MESSAGE HEADER.

Part 3.

Expanded/Remote Distribution List

Dennis Blair

LOC 17 LOC 28

LOC 37 LOC 38

LOC 39

LOC 47

LOC 48

LOC 63

Wade Hopkins

LOC 49

LOC 50 LOC 54 LOC 55 LOC 56

LOC 57

LOC 61 LOC 62 LOC 81

Part 4.

Managers,

I am sure we are in total compliance in this area but PLEASE TRIPLE CHECK!!!

I sent out a memo dated October 7, 1990 requesting that you each conduct an in-service with your staff on "KEEPING THE VEHICLE LOCKED AT ALL TIMES". I further esked that you documented this in-service and have all personnel indicate their attendance by signature and then file that in-service for later reference. Please check to make sure this task was completed.

I sent another memo dated October 16, 1990 asking that you do an immediate audit of your facility focusing on 5 specific points. Point # 4 was to double check the security efforts being observed both in the facility and in the automobile by your staff. Please check to make sure this task was completed and documented.

The reason for my concern was to avoid what now has happened. Another of our Syncor locations was found to have an unmanned, unlocked vehicle containing radioactive materials by a regulatory agency and we are now faced with \$12,000 fine (this being our third violation)! The facility was not in the Central Zone (Thank the Lord), none the less, if another violation is found within ANY Syncor facility are next level of fine will be \$100,000 and the strong potential for another double verification mandate. Obviously we do not have the staffing levels to comply with such a mandate and our company will be history.

Therefore, effectively immediately, any Syncor employee (from a CSA through myself) found leaving a Syncor delivery vehicle unlocked will be immediately terminated.

For those individuals consciously locking our vehicles every time they leave them... Thanks, and a job well done! For any individuals failing to follow this directive please be forewarned.

Please post this memo and have all members of your staff sign as having read and understood this directive. Please then file this memo with your other documentation concerning the locking of vehicles.

Thanks in advance for your corporation,

Joe Zipp Central Zone Director

Lecture Title:	Dehicle dow	locking pot	- 1
Date: 10/15	(90	0 4	1
Instructor: 1	weads 11		

Attended By The Following:

Name (Print)	Signature	Position
gayle Wedona	Dayle Mediner	
Waret Welch	- Many Pelse-	
Steve Hilton	Have tollow	RPh
	1000	L RAL
Don Paullett	1 E. Dorly C.	R.M.
Eric Boehmer	Ry Voller	
Roger Redviguez	Jean Jean	
Toe Villaveal	Joseph Villa	R. Driver
Jose Materiala	129445 J	
12 Teland Broken	Robert Dellar	PRIME
Marle Elizalde	Miller Ben de	Divar
Terry tontane	Lent Tartano	Driver
Miky Reyna	77.	
Tom Thread & !!	(The /)	/ Glarmacist
Bolo Ptace E		
DUW TTRCC C	13.6 GTach	

Topics Covered: Nectosity of locking vehicles at all -times, whenever it is left unaffected, regardless of presence presence of RAM.

```
"Joe Zipp / MCT ID: 349-7810
10:
         Dennis Plair / MC) III 403-2177
         LOC 17 / MCT ID: 349-6733
         LOC 28 / MCI ID: 347-6745
         Lac 37 / Mot the 348 4762
         1.00 38 7 MC1 318 SAC-6765
         LOC 39 / MCI 10: 343-6770
         LOC 47 / MC) 11tt 341-6794
         LOC 48 / MCT JDI 342-6795
1115
701
         LOC 63 / MOI III 345-6982
1116
         Wade Hopkins / MCT ID: 411-1616
         LOC 49 / MOT JUL 343-6796
         LOC 50 / MCT (D) 344-6797
TRE
         LOC 54 / MCI IIII 340-6803
         LDC 55 / MCT 101 341-4804
101
         TOC 56 / MOI III 342-6805
The
         LOC 57 / MCI ID: 344-6807
10:
         LOC 61 / MCI III 343-6877
       * 1.00 62 / MCI ID: 345-6879
TO:
         LOC 81 / MC1 1D: 349-6911
Subject: LOCKING OF VEHICLES
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Wed Oct 10, 1990 9145 an EST

Managers,

Please be sware that we are in deep trouble with the regulatory madies about leaving our delivery vehicles unlocked and unmanned while they contain RAM shipments. Please be foregarded that any internal audit finding a vehicle unlocked will immediately drop your pharmacy out of the satisfactory category. Again please remember that bonus payoutis directly related to your location's regulatory performance.

Therefore, elense meet with your staff and document that meeting as an in-service, with signatures of all personnel "ctending and file that document.

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Flouse remember as manager, it is your responsibility to monitor and assure compliance in the area.

Thanks, Joe

Commandt

ttended By The Followin	ng:	
Name (Print)	Signature	Position
Vike arettelal	Mushetteta	Pharm
Billy Well	Billy well	Tech
Bill Cante	Billand	Tech
Bao Vangen	Ba	Pharm
no rjuyen	98	1 / Carrin
uzy Cole	L'Cole,	Asst. Sup
Bill Polemon	is Plen	_ CSA

SYNCOR' REVIEWED MONTRY WITH ALL EMPLOYEES

TO: ALL EMPLOYEES

FROM: MICHAEL MULLIN

RE: VEHICLE SECURITY AND PACKAGE HANDLING

I was recently informed by senior management, in no uncertain terms, that due to the direct observations of an NRC and a corporate auditor the potential exists for a serious incident involving unsecured vehicles and radioactive materials. So that this serious problem can be rectified and resolved quickly the following procedures will be followed and adhered to by everyone.

- 1. Each individual is responsible for providing security to their car. DO NOT rely on the presence of another person in the vicinity. This means that if you have to walk away from the car that contains doses or returns you must lock the doors, put up the windows and lock the latch. No matter how briefly you plan to leave the car it must be secured. There will be no exceptions.
- 2. There will be direct surveillance of the 1st and 2nd run by members of the professional staff. You should NOT expect these people to provide security for your vehicle. They are there to make sure you are loading or unloading properly. There will also be spot checks here and at hospitals to ensure compliance.



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 There will be weekly training sessions to review related material.

. . .

- 4. All boxes are to be properly braced prior to leaving the parking lot.
- 5. All boxes incoming and outgoing will leave the building through the loading dock. Make sure that someone is on the dock when putting your packages there. The only exception will be when you have 1 or 2 boxes and can carry them in or out in one trip.
- 6. Due to the serious and sensitive nature of this problem anyone found violating these procedures can and will be discharged (fired) from the company.

LOCATION 72 FOLCROFT PA SYNCOR VEHICLE SECURITY AUDIT FORM

DATE :

TIME :

AUDITOR :

WHERE AUDIT TOOK PLACE:

TAG NUMBER OF OBSERVED VEHICLE :

DRIVER UNDER OBSERVATION :

AUDIT CHECKLIST : 1. ALL DOORS LOCKED

2. WINDOWS UP

3. HATCH LOCKED

4. MATERIALS BRACED

AUDITOR COMMENTS.

forty September 20, 100 100 100 100 William Fr THIS FIRMULAS TO SE CONSIDERED A URITTEN WARMING TO WORDLE WAS LEVIES A VERTILIS CONTINUED. THAT INSPITIONAL WILL SE TERMINARES IN THIS CONDITION COURS. IT S VEHICLE MUST BE LIGHED AT AUL TIMES THAT THE JADVER OF THAT VEHICLE IS NOT BOTHER OF THE TERROLE OF WITHIN THE WAY SILENUTH OF THAT SENTRES THE VEHICLE TOTAL STRANG TO CONTAIN AADIDACTIVE WATERIAL PER THE MERMIN FIGURE COURSE. Chan Germet RETURNED TO YOUR REGIONAL HAVAGER BY 10/5/70. CONTRACTOR OF WELL IN PRESENTATION MARI HETTERE, TONE DIRECTOR Catef Fire C Sep (170 1515) add Tel Lat 04 To: 140 14 101 140 25 Tur Rudney Prosser Tot Peter van der Wal Tur Leff Double Char. Diduect Sout After Untare

Date: From: Mon Sep 24, 1990 10:24 am EST Gary Redmore / MCI ID: 347-2587

TO:

* LOC 13 / MCI ID: 345-6727

Subject: (Forwarded) REGULATORY UPDATE

THIS MEMO IS TO BE CONSIDERED A WRITTEN WARNING TO ANYONE WHO LEAVES A VEHICLE UNSECURED. THAT INDIVIDUAL WILL BE TERMINATED IF THIS CONDITION OCCURS. THE VEHICLE MUST BE LOCKED AT ALL TIMES THAT THE DRIVER OF THAT VEHICLE IS NOT EITHER IN THE VEHICLE OR WITHIN ONE ARM'S LENGTH OF THAT VEHICLE. THE VEHICLE DOES NOT HAVE TO CONTAIN RADIOACTIVE MATERIAL FOR THE TERMINATION TO OCCUR.

ALL EMPLOYEES IN THE BASTERN ZONE ARE TO SIGN AND DATE THIS MEMO. IT IS TO BE RETURNED TO YOUR REGIONAL MANAGER BY 10/5/90.

YOUR COMPLIANCE WITH THE ABOVE IS APPRECIATED.

THANK YOU.

GARY REDMORE, ZONE DIRECTOR

TO:

EASTERN ZONE MANAGERS

FROM:

RODNEY PROSSER GARY REDMORE

DATE:

9/8/90

RE:

REGULATORY ITEMS

On Wednesday, Rodney Prosser spent the morning with the NRC discussing recent regulatory violations that may have occurred in NRC Region One.

The NRC was very concerned about the blocking, bracing, and security of our packages. In addition to this, we received a violation for not completing the training as stated in our license application. By next week I would like each location to evaluate these items and comply with the following.

1. Every authorized user is to read the license application(s) by the end of October 1990. We are bound to this application. It is impossible for authorized users to comply, if they do not know what is in the application. All new authorized users are to read the license application(s) during their first four weeks of employment. Each authorized user is to read both State and NRC license applications on an annual basis. This is to be documented on the RS-59 form.

- 2. Every manager is to evaluate blocking, bracing and security of the radioactive packages. Three years ago, we received a violation for this in Region One and it resulted in a \$10,000 fine. At this point, I do not know what the NRC will implement as a result of the most recent violation. During your audits, I would like you to emphasize this area. Do spot inspections on your drivers. These inspections should be unannounced. They can be accomplished by waiting for your driver at the Nuclear Medicine Departments and escorting them to the parking lot. Make sure the delivery personnel are complying with the following:
 - 1. The vehicle is locked.
 - Case covers or flip cards are being used.
 All packages including returns are secured.

I realize, that locations secure the packages in different ways. You should have an accepted method for your location and it should be followed. If you use cables in one car, then you should use cables in all cars.

It is important that the delivery personnel recognize the seriousness of a repeat violation in Region One. The next violation will cost us thousands of dollars. In addition to the fine, the cost of corrective action could be astronomical. How would you like to send two drivers on every run (one to drive and the second to verify the fact that the driver locked his car.)

Last of all, make sure that all drivers know that if they fail to secure their packages it could result in termination. The bottom line is that we can not afford another violation in this area.

I wish to thank Rodney for being concerned enough to provide the direction shown in this memo.

Have all employees sign this memo and return it to your Regional Manager.

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Loc18

Lecture Title:	Vehicle	Sewity Mems	
Date:	7/26/90		
Instructor:	Memo	/	

Attended By The Following:

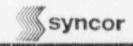
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Topics Covered:	1	The second secon

Claude Jolicoeur Jr. Claudystroning, C.S.A.

Date: 9/26/90		
Instructor: McMa	*	
Attended By The Followin	ng:	
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Vehicle Security Policy - Stry Reomore

Lecture Title: Val.	de Security	Memo
Date: 9/26/90	CONTRACTOR SERVICES	
Instructor: Memo		
Attended By The Followin	g:	
Name (Print)	Signature	Position
SHARON BARZON STANGEY SUZMON DAVE HOWELL LITE VAND DER WINE JOSEPH Fery	David R. House	CSA C
Topics Covered:		



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YOUR COMPLIANCE WITH THE ABOVE IS APPRECIATED.

THANK YOU.

SARY REDMORE, ZONE DIRECTOR

Loc 19

RECEIVED

OCT 9 1990

GARY REDMORE

iate line. Thank you,	
wan less	15/2/90 DATE
Kathleen Soutdio	16/2/90 DATE
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Forwarded message		
Please sign and date on the appropria	ete line. Thank you.	
VINCENT RIZZO	The out teres	10/2/90 DATE
KATHLEEN SERVIDIO	Kithleen Soundin	16/2/90 DATE
JAMES ANDERSON	Atox aloderon	10/1/90 DATE
NORMAN BECKMANN	Vilraman Besham	10 /2 / DATE
SANTOS MARTINEZ	- DISABLED -	DATE
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TYRONE CONGERY	"Tyrone Congerer	1012190 DATE
SALVATORE MAZZARISI	Materie Moss Cers	10/02/90 DATE
RICHARD GLENN	Redund & Dlan	10/2 /90 DATE
JAMES MARTINEZ	James Martines	10/3/90 DATE
ERNEST FREEMAN	0	DATE
KEVIN KELLY		DATE
CATHERINE PALLAY	222	10/3/98 DATE
JOHN MUNAFO (VACATION PT)		DATE
ALLEN LA VALLEY	allenentaken	10/2/90 DATE
RALPH POGOLOFF	-	10/3/20 DATE
JOSEPH MELONE	Joseph Delone	10/3/90 DATE
DOUGLAS MARSHALL		DATE
ANTHONY SICA	Million A Secon	10/2/90 DATE
TAMES GORMAN	1	DATE

LOC 06 / MCI ID: 045-6714 101 LOC 07 / MCI ID: 347-6716 TOIL LOC 13 / MCI ID: 345-6727 TOP LOC 18 / MCI ID: 349-6784 TOI LOC 19 / MCI ID: 341-6736 -oc 34 TELS LOC 24 / MCI 1D: 343-6741 TO: LOC 26 / MCI ID: 345-6743 LOC 29 / MCI ID: 348-6746 TOI TO LOC 34 / MCI ID: 349-6750 TOOLS LOC 71 / MCI ID: 045-6095 LOC 72 / MCI ID: 347-6897 TOI LOC 73 / MCI ID: 348-6898 TOR LDC 80 / MCI ID: 362-2436 TOI LOD 88 / MOI ID: 364-2551 TOI Drian Dender / MCI ID: 394-0824 TOI Rodney Prosser / MCI ID: 405-6162 TOI * Peter Van Der Wal / MCI ID: 381-8998 TO: Jeff Dzieweczynski / MCI ID: 430-2885 Joe Fery / MCI ID: 434-0399 TOI CCI Syncor EMS: Syncor / MCI ID: 302-7225 MBX: Jack Coffey Subject: (Forwarded) REGULATORY UPDATE

Message - Id: 03900924152430/0003472587NB4EM

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DARY REDMORE, ZONE DIRECTOR

Forwarded message

Date: Frz. 7 Sep 1990 10:50 edt

Vie: 1

Via: 1

To: 100 03

To: 100 04

To: 100 06 To: 10c 07

Tot loc 13

To: loc 10 To: 100 19

Tot loc 24

To: 1 oc 26

Tot loc 29

Tot 100 34

Tot loc 71

To: 10c 72

relissa Merill L. Juntu 10/2/90

Care N De Light 10/2/90

LOCKING YOUR VEHICLE/SECURING PACKAGES

I UNDERSTAND IT IS MY RESPONSIBILITY TO KEEP Lecture IIIIe: MY VEHICLE LOCKED AT ALL TIMES, FAILURE TO DO

Date: SEPTEMBER 11, 1990

Instructor: DOUG HUZAR

Attended by the following:

Unio (Print)	Signature	Position
DOUG HUZAR DAVE LAMONT CLIFF SALLALE DOUG ESAMCY ANNETTE HUTCHINGS JOHN MCAVENEY MARIO INGACOLA PAUL HARRINGTON PAULA GERGIA GODFREY RUPIA ARTY DUFFY KAREN FOWLER BERNIE ESANCY DAVE HANNUS BILL CONNORS BILL CONNORS BILL HARMAN MARK PACKARD JIM MALONE FRANK KVASNICEK RASSAD MUNIR	Part Hands	

Imples Covered:

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Via: 1

Via: 1

To: 10c 03

To: 100 04

To: 10c 06

To: 10c 07

To: 10c 13

To: loc 18

To: 100 19

To: 100 24

To: 100 26

To: 100 29

To: 100 34

To: loc 71

To: 10c 72

To: 100 73

To: 100 80

To: loc 88

To: Rodney Prosser

To: Peter van der Wal

To: Jeff Dzieweczynski

To: Joe Fery

Subject: REGULATORY UPDATE

Ca: Syncor

EMS: Syncor

mbx: Jack Coffey

TO: EASTERN ZONE MANAGERS

PROM: RODNEY PROSSER

GARY REDMORE

DATE: 9/8/90

RE: REGULATORY ITEMS

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Partile RMEach

Mishform

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End forwarded message

End forwarded message

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MANAGER: Of Crubo 9-24-90

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C.S.A.

MANAGER:

W. Shady 9/25/90 P. Coralt 9-25-50

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MANAGER: Plant 9-25-30 Jama P. Hickory

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MANAGER: P. Coult 9-25-90

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MAN. GER: Oth Corall 9-25-90
Herbertw. Hoffman

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C.S.A.

MANAGER:

Sould I paylet

Frank Inc KEESDE, RICHARD / SYNCOR/00 - HPDesk print. Message. Dated: 11/26/90 at 0956. Subject: Security Violations Sender: Randy ASMUS / MCI/GW (*) Contents: 4. TO: Richard KEESEE / SYNCOR/00 Part 1. TO: Richard KEESEE / SYNCOR/00 Part 2. MESSAGE HEADER. Part 3. Expanded/Remote Distribution List LOC 01 LOC 02 LOC 05 LOC 08 LOC 09 LOC 11 LOC 23 LCC 25 LOC 27 Steve Shipper Curt Blaum Part 4. All Managers: In the past several weeks much attention and concern has been placed on the very important issue of security violations involving customer service assistants leaving radioactive material unattended and unlocked in delivery vehicles. I have discussed this matter with each of you to assure that 100% compliance is in immediate effect. My concern lies with the insurance that this problem does not ever present itself again. Never, ever, zero again!!!! I do not have to reiterate the consequences that will come about as stated in Gene's letter to the entire company. Zero defects will be achieved only if we have the proper training and support from the local manager and professional staff. THE FOLLOWING STEPS MUST BE INSTITUTED IMMEDIATELY TO FURTHER ADDRESS THIS SERIOUS PROBLEM. 1. A RS-59 form must be read and signed by all employees and filed in the RS-59 and employee files. 2. All new employees will be trained by a professional staff member reguarding this matter emphasizing the ramifications resulting from past NRC violations. (include Genes's letter for emphasis). 3. Manager and professional staff MUST continually monitor and audit the drivers for compliance.

- 4. A local policy must be developed and posted throughout the facility. The policy should include disiplinary actions that will be taken if 100% compliance is not met. No excuses will be accepted. A minimal of one written warning and the next occurance would be termination. The RS-59 documentation can serve as the first warning.
- 5. Regional manager will audit local policy and hold the manager accountable for it's implimentation and compliance.
- 6. A minimal 4-6 month training and review should be performed to assure ongoing compliance. Make this a normal quarterly R/S function.
- 7. Develop a form to be used to document each employees receipt of training. An example follows:

SECURITY TRAINING DOCUMENTATION

EMPLOYEE SIGNATURE	DATE	
TRAINER	LOCATION	

I have read the following information concerning radioactive material security and have been trained and understand all NRC, Syncor and local policies.

- All drivers are required to lock their unattended vehicles when returning to the radiopharmacy for additional cases.
- An individual must be placed in the parking lot to maintain constant surveillance of the unlocked, unattended vehicle.
- All radioactive material packages must be locked in vehicles or attended to during deliveries to hospitals or final destinations.
- Failure to comply with these procedures will lead to severe disiplinary actions and/or termination.

Please remember that this must be a continued compliance effort with careful auditing and monitoring. We cannot survive any further NRC violations of this type.

Thank you for your concern of this matter.

Randy.

TO:

ALL SYNCOR EMPLOYEES

FROM:

GARY REDMORE

DATE: SEPTEMBER 24, 1990

SUBJECT: REGULATERY UPDATE

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THANK YOU.

GARY REDMORE, ZONE DIRECTOR

SIGNATURE: Oaniel Carzmant



Syncor*

TO:

ALL SYNCOR EMPLOYEES

FROM:

GARY REDMORE

DATE:

SEPTEMBER 24, 1990

SUBJECT: REGULATERY UPDATE

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THANK YOU,

GARY REDMORE, ZON DIRECTOR

SIGNATURE:

DATE:



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FROM:

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GARY REDMORE, ZONE DIRECTOR

DATE: 11/10/90



Innovators in high-tech pharmacy services

TO:

ALL SYNCOR EMPLOYEES

FROM:

GARY REDMORE

DATE:

SEPTEMBER 24, 1990

SUBJECT: REGULATERY UPDATE

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SIGNATURE: Charl Horson DATE: 11 - 10 - 90



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/carso

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SEPTEMBER 24, 1990

SUBJECT: REGULATERY UPDATE

THIS MEMO IS TO BE CONSIDERED A WRITTEN WARNING TO ANYONE WHO LEAVES A VEHICLE UNSECURED. THAT INDIVIDUAL WILL BE TERMINATED IF THIS CONDITION OCCURS. THE VEHICLE MUST BE LOCKED AT ALL TIMES THAT THE DRIVER OF THAT VEHICLE IS NOT EITHER IN THE VEHICLE OR WITHIN ONE ARM'S LENGTH OF THAT VEHICLE. THE VEHICLE DOES NOT HAVE TO CONTAIN RADIOACTIVE MATERIAL FOR THE TERMINATION TO OCCUR.

ALL EMPLOYEES IN THE EASTERN ZONE ARE TO SIGN AND DATE THIS MEMO.

YOUR COMPLIANCE WITH THE ABOVE IS APPRECIATED!!

THANK YOU,

GARY REDMORE, ZONE DIRECTOR



Innovators in high-tech pharmacy services

TO:

ALL SYNCOR EMPLOYEES

FROM:

GARY REDMORE

DATE:

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SIGNATURE: 3/200 tas

KEESEE, RICHARD / SYNCOR/00 - HPDesk print.

Rulade Fine

Message. Dated: 11/19/90 at 1239.

Subject: Securing of delivery vehicles

Sender: Greg HIATT / MCI/GW Contents: 4.

TO: Richard KEESEE / SYNCOR/00

Part 1.

TO: Jack COFFEY / SYNCOR/00 Richard KEESEE / SYNCOR/00

Part 2.

MESSAGE HEADER.

Part'3.

Save for documentation

Expanded/Remote Distribution List

LOC 12 LOC 14

LOC 21 LOC 22

LOC 40

LOC 84 LOC 85

LOC 44

LOC 45

LOC 65

LOC 46 LOC 41

LOC 42

LOC 43

Loc 32

LOC 87

Susan Aggarwal

Jay R. Simon

Part 4.

November 19, 1990

TO: Pharmacy Managers

From: Greg Hiatt Western Zone Director

Managers:

I am sure you have all read about the recent violation Syncor received from the NRC due to improperly securing our delivery vehicles. As it has in the past, Regulatory is again reminding us that we need to monitor the loading and unloading of our vehicles.

In case you need additional guidance, Regulatory has printed a couple of articles on two of the hottest compliance items. These article can be found in the November 1990 issue of "Regulatory Briefs".

Because of the importance of the issues covered, I want everyone involved in the regulatory programs within the Western Zone to be absolutely certain that they review and understand the information contained in these articles. The first article pertains to compliance and the recent violations in NRC Regions I and III, and the second topic, a very important issue with all regulatory agencies, pertains to performing bioassays.

As Managers, we must be certain that we are following the company guidelines for the preparation of radiopharmaceuticals (November 1, 1990 revision), that we keep up with our paperwork (no falsification of records), and that we secure radioactive products at all times (outer facility doors secured, delivery vehicles secured). Of course there are more issues that we need to keep on top of but the current "hot" issues are stated above.

Let's not let the Company down.

Thanks,

Greg Hiatt

From Richard Keesee's recent message on the violation:

These violations were found by the NRC inspector who visited the Folcroft site on August 9, 1990.

* The violation for which the fine is proposed involves two instances of *radioactive material allegedly left unattended and unsecured in unlocked *vehicles in an unsecured parking lot. In one instance, the keys were left in *the vehicle and the motor was running.

In a letter informing the company of the inspection findings and the proposed enforcement action, Thomas I. Martin, Regional Administrator of NRC Region I, pointed out that NRC Inspectors had found similar incidents involving failure to secure radioactive materials in unrestricted areas during inspections of sites in Grand Rapids, Michigan and Hartford, Ct. in 1985.