syncor®

September 17, 1990

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

Gentlemen:

This is our " **REPLY TO NOTICE OF VIOLATION** "

Violations Assessed Civil Penalties

I. A. License Condition No. 19 requires, in part, that the licensee process radioactive material with reagent kits in accordance with the instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the reagent kit.

The brochure furnished by the manufacturer of the Tc-99m Medronate Reagent Kit used by the licensee on April 28, 1988 for compounding Tc-99m methylene diphosphonate (MDP) for bone imaging requires that sodium pertechnetate Tc-99m be slowly injected into the reaction vial.

Contrary to the above, on April 28, 1988, the licensee processed sodium pertechnetate Tc-99m with Tc-99m Medronate reagent kits in the preparation of Tc-99m MDP by injecting saline into the reaction vials supplied by the manufacturer, withdrawing the contents, adding the contents to a larger evacuated vial, and then adding sodium pertechnetate Tc-99m to the contents.

REPLY:

This violations is admitted.

The violation occurred because pharmacist were combining several kits of the same lot to satisfy a commitment previously made to the NRC concerning the use of a computer traceability program.

0346

Syncor International Corporation • 20001 Prairie Street • Chatsworth, California 91311
(818) 886-7400 • FAX 886-6028 • Telex MCI 67-18642 Syncor CHATS

Corrective Action

The procedure of injecting saline into the reaction vial supplied by the manufacturer, withdrawing the contents, adding the contents to a larger evacuated vial, and then adding sodium pertechnetate Tc-99m to the contents was discontinued prior to the inspection conducted by your office July 6-8, 1988.

Corrective Action to Avoid Further Violations

A directive discontinuing this practice was issued by the Chairman of the Radiation Safety Committee on July 21,1988. A similar memo was issued on April 16, 1990 by the Corporate Radiation Safety Officer. This directive included a statement that a violation of this directive would result in appropriate disciplinary action up to and including termination.

Full compliance with this violation was achieved by August 5,1988.

B. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed materials be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item K.2, that sodium pertechnetate elution will be checked routinely for alumina breakthrough and that no eluate will be used if it exceeds 15 micrograms of alumina per milliliter of eluate.

Contrary to the above, sodium pertechnetate elution were not routinely checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for preparation and dispensing of technetium-99m (Tc-99m) radiopharmaceutical in at least the following examples,

1. On August 8, 1988, six elutions of sodium pertechnetate from the molybdenum 99/technetium 99m generator were made but five of the six elutions were not checked for alumina breakthrough and the resulting eluate with an unknown alumina content, was used for the preperationn and dispensing of radiopharmaceuticals.

2. On August 9, 1988, eight elutions of sodium pertechnetate from the molybdenum-99/technetium-99m generator were made but seven of the eight elutions were not checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for the preparation and dispensing of radiopharmaceutical.

REPLY:

This violation is denied

Reason for denial: The application dated November 20, 1983 Attachment 2 Item K.2, which is referenced as a source for this violation. The statement that elutions will be checked routinely made in that application referred to the routine that was used in 1983. In 1983 only the first elutions from Mo99-Tc99m generators were routinely checked for alumina content, and it was not routine practice to check each elution from a Mo99-Tc99 generator. According to the pharmacist involved in this violation this was the way that she was taught to do routine alumina checks by the manager. She apparently falsified records but felt she was performing these checks in accordance with the way she had been instructed to do it by the manager and RSO.

Based on the reference from the November 20, 1983 application this violation is denied. We also are not aware that any alumina content checks have ever exceeded a quantity greater then 10 micrograms per milliliter eluate in the past eight years.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplement VI).

Cumulative Civil Penalty - $15,000 (assessed equally between the two violations).

II. 10 CFR 30.9(a) requires information provided to the Commission by a licensee or information required by the Commission's regulations or license conditions be complete and accurate in all material respects.

License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed material be used in accordance with statements, representations and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 2., 1983 provides in Item 17, Appendix I that records will be kept of daily surveys of elution and preparation areas.

Contrary to the above, on at least one occasion in May or June 1988, the record kept of the daily survey of the licensee's elution and preparation areas was not accurate in that survey readings were falsified by a licensee employee at the direction of a licensee management official.

REPLY:

This violation is admitted.

This violation occurred because the employee in question was directed by the manager and RSO to complete, after the fact, a survey record. She was directed to falsify this record a second time by the manager during the NRC investigation on August 24, 1988. It should be noted that the employee refused to falsify or enter data into the record a second time when ordered to do so by the manager. Immediate corrective actions were taken at that time by the employee by her refusal.

Corrective Actions

At the time that this violation was identified by Syncor personnel and voluntarily pointed out to the NRC investigator falsification of survey records was no longer being done. On April 29, 1988 a memo concerning falsifying of records was sent to all Syncor locations by the chairman of the Syncor Radiation Safety Committee. Follow up visits were made by members of the health physics staff for training and auditing purposes. Actions were taken to insure that procedures were implemented and done properly. Following the July NRC inspection additional corrective actions were taken in accordance with the confirmatory action letters of July 13 and September 2, 1988. Note that as a result of this violation the manager was demoted to staff pharmacist and subsequently resigned from Syncor.

Corrective Action to Avoid Further Violations

We now spend one hour in the Syncor Authorized User Training Program discussing the seriousness of "Falsification of Records." In addition the Quality and Regulatory auditors place special emphasis during the audit on record falsification.

It is stressed to all employees that Syncor's policy is that falsification of records will not be tolerated. When such actions are identified, disciplinary action will be taken up to and including termination.

Full compliance was achieved by the September 12-15, 1988.

This is a Severity Level III violation (Supplement VII).

Civil Penalty - $5,000.

Violations Not Assessed a Civil Penalty

III. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires licensed material to be used in accordance with statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item (I) that all radiopharmaceutical dispensed from the nuclear pharmacy shall bear a prescription number and the proper label.

Attachment 2, Item (J) of the reference application requires that each dose container be labeled to include, among other information, the pharmaceutical form.

Attachment 2, Item H.1.a. of the referenced application requires that a prepared Radiopharmaceutical Data Sheet be completed for each radiopharmaceutical prepared in house and included the chemical form of the radionuclide.

A. Contrary to the above:

1. On April 28, 1988, 17 radiopharmaceutical doses which the licensee distributed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. The dose containers listed the pharmaceutical form as TC-99m methylene diphosphonate (MDP) when the actual pharmaceutical form was Tc-99m sodium pertechnetate.

2. On April 28, 1988, a Radiopharmaceutical Data Sheet prepared by the licensee did not include the correct chemical form of the radionuclide in that it incorrectly listed the chemical form of a radiopharmaceutical prepared in-house as methylene diphosphonate when the actual chemical form of the radionuclide was Tc-99m sodium pertechnetate.

B. Contrary to the above, on June 9, 1988, three radiopharmaceuticals which the licensee distributed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. The dose containers listed the pharmaceutical form as Tc-99m MAA (Technetium Tc-99m Albumin Aggregated) when the actual pharmaceutical form was Tc-99m DTPA (Technetium Tc-99m pentetate).

C. Contrary to the above, On October 8, 1987, one radiopharmaceutical which the licensee dispensed from the nuclear pharmacy did not have a proper label in that the incorrect pharmaceutical form was listed on the dose container label. The dose container listed the pharmaceutical form as Tc-99m MAA (Technetium Tc-99m albumin aggregated) when the actual pharmaceutical form was Tc-99m sodium pertechnetate.

REPLY

Violation III,A. 1,& 2 are denied

Reason: We have substantial evidence that the material (methylene diphosphonate (MDP) distributed on April 28, 1988 was in fact MDP and not Tc-99m sodium pertechnetate. Although we do not have proof for the specific lot of MDP referenced in this violation we have a strong reason to deny this violation. We experienced a similar situation where Tc-99m was added to a vial which had been previously used and contained some residual MDP. This occurred at our Cleveland location.

A original vial of MDP which had all of the activity dispensed except for approximately 15 millicuries was mistakenly used to prepare a new lot of the product. 400 millicuries of Tc-99m was added to this vial and doses were dispensed from this material after quality control had been performed and was within the pharmacopeia acceptable limits. The material did however results in inadequate scan quality. When quality control was performed on it at a customers request it indicated a 20% MDP tag with 80% free pertechnetate.

In order to confirm that the results could be repeated an experiment duplicating the above situation was performed and a lot of MDP was prepared using 400 millicuries of Tc-99m. All of the material except approximately 15 millicuries was discarded and an additional 400 millicuries of Tc-99m was added to the vial. Quality control was performed on this material and was acceptable. One hour later the quality control test was repeated and indicated a 20% MDP tag and 80% free pertechnetate.

With the knowledge that we now have concerning what was distributed to the customer we are certain that MDP was distributed to area hospitals not Tc-99m sodium pertechnetate. Because of the residual MDP in the vial used to make up the suspect lot, a tag did occur. It is however most likely that because of lack of MDP in the vial the product did not remain stable and a high percentage of Tc-99m pertechnetate was present in the product which was injected into the patient.

Violations B & C

These violations are admitted.

Reason: Human error

Corrective Actions

On April 29, 1988 a directive from the Radiation Safety Committee was sent to all locations concerning quality control and falsification of records.

On June 1, 1988, the Quality and Regulatory department sent a health physicist to Syncor Blue Ash to train the following individuals:

a. QC Technologist - QC Procedures

b. Pharmacist - Efficiencies, LLD, Bioassay, Air Monitoring, QC, Dose Calibrator Consistency Checks.

A program was put in place to evaluate QC Technologist competency. This competency is to be checked by using a double blind study for product tagging.

A directive was issued that when assaying doses, product quantity and volume must match those values printed on the prescription.

Corrective Actions to Avoid Further Violations

Syncor created and implemented a generic quality control manual. It is required to be used at all Syncor locations.

The Syncor Quality and Regulatory Department is now auditing compliance of the Corporate Quality Control policies. In addition, a computer software program has been written and implemented for documenting product quality control results.

In an effort to retain product identity, Syncor has introduced a pilot program using clear lead glass vial shields. We are still evaluating these shields since their advantages may be offset by their size and weight.

We have modified the Syncor Authorized User Training Program to include 8 hours of theoretical and laboratory experience. This experience relates to the quality control of Technetium radiopharmaceuticals and the importance of doing "Quality Control". The text for this portion of the course is the "Syncor Quality Control Procedures Manual."

Product quality control procedures must be completed on all compounded products before they leave the pharmacy.

Finally we have retained the services of a human factors engineer recommended by NRC personnel to aid in identifying those factors which contribute to human error leading to misadministrations.

Full compliance was achieved by September 12-15, 1988

These violations have been classified in the aggregate as a Severity Level III problem (Supplement VI).

IV. License Condition No. 23 of Byproduct Material License No. 34-18309-01MD requires licensed material to be used in accordance with statements representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983

A. The referenced application, dated November 20, 1983, states in Item 10 that Cobalt-57, Barium-133 and Cesium-137 reference standards will be used to determine the accuracy of the licensee's dose calibrators.

Contrary to the above, from March 4, 1987, to May 21, 1988, a Barium-133 reference source was not used to determine the accuracy of the licensee's dose calibrators.

Reply

The violation is admitted.

Reason: This Ba-133 source was in storage and the manager made the decision that it was unnecessary to use it.

Corrective Action

A directive was given to all individuals performing the dose calibrator accuracy test that all specified standards be utilized to perform this test.

Corrective Action to Avoid Further Violations

A computer file has been established to identify all tests performed on a periodic basis with the frequency required for the test and the date by which the test must be completed.

Full compliance was achieved on August 17, 1988

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

B. The referenced application, dated November 20, 1983 states in Item 21.(B).(3) that the fume hood will be checked every six months with a voltmeter to determine if the fume hood is operating according to specifications.

Contrary to the above, during the period October 21, 1987 through July 6, 1988, a period exceeding six months, the fume hood was not checked with a volumeter to determine if the fume hood was operation according to specifications.

Reply

This violation is admitted

Reason: Company policy requires that this dertermination be done by a member of the Quality and Regulatory auditing staff. The auditor failed to perform the procedure and the RSO did not check to insure that it had been done.

Corrective Action

The Quality and Regulatory auditor was directed to perform a fume hood ventilation check at his next scheduled visit.

Corrective Action to Avoid Further Violations

This procedure is listed in a computer tickler file. Quality and Regulatory auditors have been directed to perform this check at each visit to ensure that the fume hood ventilation requirements are met and that the frequency required for performing this check is satisfied.

Full compliance was achieved on August 31, 1988

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

C. License Condition No. 14.A(1) requires each sealed source containing licensed material, other than Hydrogen-3, with a half life greater than 30 days and in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, as of July 6, 1988, the date of the inspection, a sealed source containing a nominal 148 microcuries of Barium-133 which has a half-life of greater than 30 days and in solid form, had not been tested for leakage since at least March 1986, a period in excess of six months.

REPLY

This violation is admitted.

Reason: The Ba-133 source was in storage and the manager had been notified that sealed sources in storage were not required to be leaked tested.

Corrective Action

The source in question was leak tested on July 5, 1988 and full compliance was achieved as of this date.

Corrective Actions to Avoid Further Violations

Not Applicable: Our present license specifies that sealed sources which have been placed in storage do not have to be leak tested.

This is a severity level IV violation (Supplement VI).

Following are the two items that you requested that we address in light of the O.I. investigation.

1. Actions (for example, orientation, training, and periodic refresher training) taken or planned to assure that , in the future, all individuals associated with NRC-licensed activities at Syncor facilities fulfill their responsibility to Syncor and to the NRC to conduct those activities, deal with the NRC, and maintain NRC records, in a forthright and candid manner and in accordance with the requirements of 10 CFR 30.9.

2. Your basis for having confidence in the integrity of those employees involved in the violations in Sections I and II of the Notice and your basis for having assurance that those individuals will not, in the future, willfully commit violations of NRC requirements

Item 1

A series of video tapes has been produced for training Syncor personnel. Two of these programs are presented to all personnel during their orientation and prior to their beginning work. These same two tapes are used for periodic refresher training. The titles of these videos are:

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (This tape instructs personnel in their obligation to fulfill their responsibilities to Syncor and to the NRC and also informs personnel of Syncor's obligation to them as employees.)

SEVEN RULES (These are rules of required practice when working in the restricted area)

An additional 6 videos are also available for training of specific procedures; they are:

AIR SAMPLING PROCEDURES

MINIMIZING EXTREMITY EXPOSURE

QUALITY CONTROL PROCEDURES

THYROID BIOASSAY PROCEDURES

I-131 CAPSULE COMPOUNDING PROCEDURE

IODINE-131 HANDLING

All Syncor locations are audited to insure that required training has been done and is documented. A copy of the items audited as they appear on the Quality and Regulatory audit form is attached.

Item 2

Only two individuals involved in the violations in Section 1 and II remain employed by Syncor. One employee, i.e. the individual (technologist) which Syncor's investigation revealed to the OI investigator, to our knowledge completed only one false record when directed to do so by the manager. This lady was not aware at the time that following the managers directive was falsifying records.

After the inspections and investigations by the NRC she became acutely aware of this type of violation and refused to add data to records which had not been completed. This refusal was at a time when the NRC investigator was present in the facility. She also volunteered the information to the Syncor regional manager during his investigation of the events causing the problems at this location. We are not aware that this individual has ever falsified another record. She has been a conscientious and loyal employee and has been totally trustworthy. Her commitment to regulatory compliance is all the better because of her experience in this incident.

The second employee, the pharmacist who admitted falsifying the alumina records, has become a valuable trusted employee. Even though your office maintains that she willfully falsified the alumina records we feel that was not the case. She had been trained in current policy and NRC requirements didactically. She was trained on the job by an individual who refused to change to current procedures. This unquestionably confused her and caused her to be undecided about what she should do. She was also aware of what seemed to be standard procedure by the QC technologist and the manager with respect to data entry on the quality control documentation.

We maintain that if she was willfully falsifying records she would not have volunteered that information to NRC personnel. If she had been more experienced and had received on the job training consistent with Syncor's policies she would not have completed the records after the fact. If she thought that she was willfully falsifying records after the July 1988 inspection she would not have continued to enter alumina data when the test was not done.

Since the NRC inspections and investigation she has been our watch dog with respect to regulatory compliance at this location. We are not aware that she falsified alumina records beyond the August dates referenced in the notice of violation letter or any other records. We are confident that based on her experiences during this incident that she will not in the future, willfully commit violations of NRC requirements.

This concludes our reply to the Notice of Violation.

Sincerely,

Gene McGrevin

Gene McGrevin
President and C.E.O.

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

		Y	N	N/A or Comment
III.	Health Physics Evaluation L. Vehicle Review			
	3. Vehicles placarded, driver qualifications current, supporting documentation sent to corporate, and emergency equipment available on vehicle when carrying DOT III shipments 49 CFR 172.504, DOT $ Fine SL III	—	—	———
	4. Security provided during loading of vehicles. Vehicles locked when unattended 10 CFR 20.207, SL III	—	—	———
	5. Accidents reported to corporate within 24 hours of occurrence. Documented on RS-23 10 CFR 20.403, SL V	—	—	———
	6. Tests results available on all DOT type 7A shipping containers that are used 49 CFR 173.461, DOT $ Fine, SL V	—	—	———
IV.	Training (discussions with staff, records review) 10 CFR 19.12, SL V			
	A. Knowledge of staff members of license conditions and NRC Part 19.12. Proper documentation on RS-60	—	—	———
	B. Knowledge of DOT requirements, emergency procedures and of the ALARA concept. Proper documertation RS-59	—	—	———
	C. Female employees instructed in Regulatory Guide 8.13. Training properly documented on RS-60	—	—	———
	D. Dispensers trained and tested in Moly/ alumina breakthrough testing. Training documented on RS-61a and proficiency documented on RS-61b 10 CFR 30.34 (g) and 35.204, SL V	—	—	———
	E. Initial employment and periodic retraining programs conducted and documented on RS-59 Item 8, 10 CFR 19.12, SL IV	—	—	———

IV. Training

	Y	N	N/A or Comment
F. Training documentation available for personnel compounding I-131 therapy capsules	—	—	———
G. Personnel trained in the Bioassay procedure. Training documentation available	—	—	———
H. Personnel trained in Air Monitoring procedures. Training documentation available	—	—	———
I. Personnel trained in needleless WBC procedure. Training documentation available	—	—	———
J. Contamination Smear training documentation available	—	—	———

V. Regulatory (discussions with RSO)

A. Pharmacy, State Law, SL IV

1. Requested from the State Board of Pharmacy for advance approval of any remodeling, if appropriate	—	—	———
2. Advised the State Board of Pharmacy of any changes of Pharmacist in charge	—	—	———
3. Misadministrations reported to corporate RSO and documented on RS-58	—	—	———
4. Technician duties clearly defined, documented, and in compliance with State Pharmacy Laws. SL III	—	—	———
5. Used generators are not distributed for human use SL III	—	—	———

B. Personnel

1. Authorized user and pharmacist on site when radiopharmaceuticals are dispensed, labeled, handled, and/or packaged. License Condition 11, 12, SL III	—	—	———
2. Customer license file current and complete CFR 30.41 (d), SL IV	—	—	———

syncor

September 17, 1990

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

Gentlemen:

This is our " **REPLY TO NOTICE OF VIOLATION** "

Violations Assessed Civil Penalties

I. A. License Condition No. 19 requires, in part, that the licensee process radioactive material with reagent kits in accordance with the instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the reagent kit.

The brochure furnished by the manufacturer of the Tc-99m Medronate Reagent Kit used by the licensee on April 28, 1988 for compounding Tc-99m methylene diphosphonate (MDP) for bone imaging requires that sodium pertechnetate Tc-99m be slowly injected into the reaction vial.

Contrary to the above, on April 28, 1988, the licensee processed sodium pertechnetate Tc-99m with Tc-99m Medronate reagent kits in the preparation of Tc-99m MDP by injecting saline into the reaction vials supplied by the manufacturer, withdrawing the contents, adding the contents to a larger evacuated vial, and then adding sodium pertechnetate Tc-99m to the contents.

REPLY:

This violations is admitted.

The violation occurred because pharmacist were combining several kits of the same lot to satisfy a commitment previously made to the NRC concerning the use of a computer traceability program.

Corrective Action

The procedure of injecting salire into the reaction vial supplied by the manufacturer, withdrawing the contents, adding the contents to a larger evacuated vial, and then adding sodium pertechnetate Tc-99m to the contents was discontinued prior to the inspection conducted by your office July 6-8, 1988.

Corrective Action to Avoid Further Violations

A directive discontinuing this practice was issued by the Chairman of the Radiation Safety Committee on July 21,1988. A similar memo was issued on April 16, 1990 by the Corporate Radiation Safety Officer. This directive included a statement that a violation of this directive would result in appropriate disciplinary action up to and including termination.

Full compliance with this violation was achieved by August 5,1988.

B. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed materials be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item K.2, that sodium pertechnetate elution will be checked routinely for alumina breakthrough and that no eluate will be used if it exceeds 15 micrograms of alumina per milliliter of eluate.

Contrary to the above, sodium pertechnetate elution were not routinely checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for preparation and dispensing of technetium-99m (Tc-99m) radiopharmaceutical in at least the following examples,

1. On August 8, 1988, six elutions of sodium pertechnetate from the molybdenum 99/technetium 99m generator were made but five of the six elutions were not checked for alumina breakthrough and the resulting eluate with an unknown alumina content, was used for the preperationn and dispensing of radiopharmaceuticals.

2. On August 9, 1988, eight elutions of sodium pertechnetate from the molybdenum-99/technetium-99m generator were made but seven of the eight elutions were not checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for the preparation and dispensing of radiopharmaceutical.

REPLY:

This violation is denied

Reason for denial: The application dated November 20, 1983 Attachment 2 Item K.2, which is referenced as a source for this violation. The statement that elutions will be checked routinely made in that application referred to the routine that was used in 1983. In 1983 only the first elutions from Mo99-Tc99m generators were routinely checked for alumina content, and it was not routine practice to check each elution from a Mo99-Tc99 generator. According to the pharmacist involved in this violation this was the way that she was taught to do routine alumina checks by the manager. She apparently falsified records but felt she was performing these checks in accordance with the way she had been instructed to do it by the manager and RSO.

Based on the reference from the November 20, 1983 application this violation is denied. We also are not aware that any alumina content checks have ever exceeded a quantity greater then 10 micrograms per milliliter eluate in the past eight years.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplement VI).

Cumulative Civil Penalty - $15,000 (assessed equally between the two violations).

II. 10 CFR 30.9(a) requires information provided to the Commission by a licensee or information required by the Commission's regulations or license conditions be complete and accurate in all material respects.

License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed material be used in accordance with statements, representations and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 provides in Item 17, Appendix I that records will be kept of daily surveys of elution and preparation areas.

Contrary to the above, on at least one occasion in May or June 1988, the record kept of the daily survey of the licensee's elution and preparation areas was not accurate in that survey readings were falsified by a licensee employee at the direction of a licensee management official.

REPLY:

This violation is admitted.

This violation occurred because the employee in question was directed by the manager and RSO to complete, after the fact, a survey record. She was directed to falsify this record a second time by the manager during the NRC investigation on August 24, 1988. It should be noted that the employee refused to falsify or enter data into the record a second time when ordered to do so by the manager. Immediate corrective actions were taken at that time by the employee by her refusal.

Corrective Actions

At the time that this violation was identified by Syncor personnel and voluntarily pointed out to the NRC investigator falsification of survey records was no longer being done. On April 29, 1988 a memo concerning falsifying of records was sent to all Syncor locations by the chairman of the Syncor Radiation Safety Committee. Follow up visits were made by members of the health physics staff for training and auditing purposes. Actions were taken to insure that procedures were implemented and done properly. Following the July NRC inspection additional corrective actions were taken in accordance with the confirmatory action letters of July 13 and September 2, 1988. Note that as a result of this violation the manager was demoted to staff pharmacist and subsequently resigned from Syncor.

Corrective Action to Avoid Further Violations

We now spend one hour in the Syncor Authorized User Training Program discussing the seriousness of "Falsification of Records." In addition the Quality and Regulatory auditors place special emphasis during the audit on record falsification.

It is stressed to all employees that Syncor's policy is that falsification of records will not be tolerated. When such actions are identified, disciplinary action will be taken up to and including termination.

Full compliance was achieved by the September 12-15, 1988.

This is a Severity Level III violation (Supplement VII).

Civil Penalty - $5,000.

Violations Not Assessed a Civil Penalty

III. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires licensed material to be used in accordance with statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item (I) that all radiopharmaceutical dispensed from the nuclear pharmacy shall bear a prescription number and the proper label.

Attachment 2, Item (J) of the reference application requires that each dose container be labeled to include, among other information, the pharmaceutical form.

Attachment 2, Item H.1.a. of the referenced application requires that a prepared Radiopharmaceutical Data Sheet be completed for each radiopharmaceutical prepared in house and included the chemical form of the radionuclide.

A. Contrary to the above:

1. On April 28, 1988, 17 radiopharmaceutical doses which the licensee distributed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. The dose containers listed the pharmaceutical form as TC-99m methylene diphosphonate (MDP) when the actual pharmaceutical form was Tc-99m sodium pertechnetate.

2. On April 28, 1988, a Radiopharmaceutical Data Sheet prepared by the licensee did not include the correct chemical form of the radionuclide in that it incorrectly listed the chemical form of a radiopharmaceutical prepared in-house as methylene diphosphonate when the actual chemical form of the radionuclide was Tc-99m sodium pertechnetate.

B. Contrary to the above, on June 9, 1988, three radiopharmaceuticals which the licensee distributed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. The dose containers listed the pharmaceutical form as Tc-99m MAA (Technetium Tc-99m Albumin Aggregated) when the actual pharmaceutical form was Tc-99m DTPA (Technetium Tc-99m pentetate).

C. Contrary to the above, On October 8, 1987, one radiopharmaceutical which the licensee dispensed from the nuclear pharmacy did not have a proper label in that the incorrect pharmaceutical form was listed on the dose container label. The dose container listed the pharmaceutical form as Tc-99m MAA (Technetium Tc-99m albumin aggregated) when the actual pharmaceutical form was Tc-99m sodium pertechnetate.

REPLY

Violation III,A. 1,& 2 are denied

Reason: We have substantial evidence that the material (methylene diphosphonate (MDP) distributed on April 28, 1988 was in fact MDP and not Tc-99m sodium pertechnetate. Although we do not have proof for the specific lot of MDP referenced in this violation we have a strong reason to deny this violation. We experienced a similar situation where Tc-99m was added to a vial which had been previously used and contained some residual MDP. This occurred at our Cleveland location.

A original vial of MDP which had all of the activity dispensed except for approximately 15 millicuries was mistakenly used to prepare a new lot of the product. 400 millicuries of Tc-99m was added to this vial and doses were dispensed from this material after quality control had been performed and was within the pharmacopeia acceptable limits. The material did however results in inadequate scan quality. When quality control was performed on it at a customers request it indicated a 20% MDP tag with 80% free pertechnetate.

In order to confirm that the results could be repeated an experiment duplicating the above situation was performed and a lot of MDP was prepared using 400 millicuries of Tc-99m. All of the material except approximately 15 millicuries was discarded and an additional 400 millicuries of Tc-99m was added to the vial. Quality control was performed on this material and was acceptable. One hour later the quality control test was repeated and indicated a 20% MDP tag and 80% free pertechnetate.

With the knowledge that we now have concerning what was distributed to the customer we are certain that MDP was distributed to area hospitals not Tc-99m sodium pertechnetate. Because of the residual MDP in the vial used to make up the suspect lot, a tag did occur. It is however most likely that because of lack of MDP in the vial the product did not remain stable and a high percentage of Tc-99m pertechnetate was present in the product which was injected into the patient.

Violations B & C

These violations are admitted.

Reason: Human error

Corrective Actions

On April 29, 1988 a directive from the Radiation Safety Committee was sent to all locations concerning quality control and falsification of records.

On June 1, 1988, the Quality and Regulatory department sent a health physicist to Syncor Blue Ash to train the following individuals:

a. QC Technologist - QC Procedures

b. Pharmacist - Efficiencies, LLD, Bioassay, Air Monitoring, QC, Dose Calibrator Consistency Checks.

A program was put in place to evaluate QC Technologist competency. This competency is to be checked by using a double blind study for product tagging.

A directive was issued that when assaying doses, product quantity and volume must match those values printed on the prescription.

Corrective Actions to Avoid further Violations

Syncor created and implemented a generic quality control manual. It is required to be used at all Syncor locations.

The Syncor Quality and Regulatory Department is now auditing compliance of the Corporate Quality Control policies. In addition, a computer software program has been written and implemented for documenting product quality control results.

In an effort to retain product identity, Syncor has introduced a pilot program using clear lead glass vial shields. We are still evaluating these shields since their advantages may be offset by their size and weight.

We have modified the Syncor Authorized User Training Program to include 8 hours of theoretical and laboratory experience. This experience relates to the quality control of Technetium radiopharmaceuticals and the importance of doing "Quality Control". The text for this portion of the course is the "Syncor Quality Control Procedures Manual."

Product quality control procedures must be completed on all compounded products before they leave the pharmacy.

Finally we have retained the services of a human factors engineer recommended by NRC personnel to aid in identifying those factors which contribute to human error leading to misadministrations.

Full compliance was achieved by September 12-15, 1988

These violations have been classified in the aggregate as a Severity Level III problem (Supplement VI).

IV. License Condition No. 23 of Byproduct Material License No. 34-18309-01MD requires licensed material to be used in accordance with statements representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983

A. The referenced application, dated November 20, 1983, states in Item 10 that Cobalt-57, Barium-133 and Cesium-137 reference standards will be used to determine the accuracy of the licensee's dose calibrators.

Contrary to the above, from March 4, 1987, to May 21, 1988, a Barium-133 reference source was not used to determine the accuracy of the licensee's dose calibrators.

Reply

The violation is admitted.

Reason: This Ba-133 source was in storage and the manager made the decision that it was unnecessary to use it.

Corrective Action

A directive was given to all individuals performing the dose calibrator accuracy test that all specified standards be utilized to perform this test.

Corrective Action to Avoid Further Violations

A computer file has been established to identify all tests performed on a periodic basis with the frequency required for the test and the date by which the test must be completed.

Full compliance was achieved on August 17, 1988

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

B. The referenced application, dated November 20, 1983 states in Item 21.(B).(3) that the fume hood will be checked every six months with a voltmeter to determine if the fume hood is operating according to specifications.

Contrary to the above, during the period October 21, 1987 through July 6, 1988, a period exceeding six months, the fume hood was not checked with a volumeter to determine if the fume hood was operation according to specifications.

Reply

This violation is admitted

Reason: Company policy requires that this dertermination be done by a member of the Quality and Regulatory auditing staff. The auditor failed to perform the procedure and the RSO did not check to insure that it had been done.

Corrective Action

The Quality and Regulatory auditor was directed to perform a fu hood ventilation check at his next scheduled visit.

Corrective Action to Avoid Further Violations

This procedure is listed in a computer tickler file. Quality and Regulatory auditors have been directed to perform this check at each visit to ensure that the fume hood ventilation requirements are met and that the frequency required for performing this check is satisfied.

Full compliance was achieved on August 31, 1988

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

C. License Condition No. 14.A(1) requires each sealed source containing licensed material, other than Hydrogen-3, with a half life greater than 30 days and in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, as of July 6, 1988, the date of the inspection, a sealed source containing a nominal 148 microcuries of Barium-133 which has a half-life of greater than 30 days and in solid form, had not been tested for leakage since at least March 1986, a period in excess of six months.

REPLY

This violation is admitted.

Reason: The Ba-133 source was in storage and the manager had been notified that sealed sources in storage were not required to be leaked tested.

Corrective Action

The source in question was leak tested on July 5, 1988 and full compliance was achieved as of this date.

Corrective Actions to Avoid Further Violations

Not Applicable: Our present license specifies that sealed sources which have been placed in storage do not have to be leak tested.

This is a severity level IV violation (Supplement VI).

Following are the two items that you requested that we address in light of the O.I. investigation.

1. Actions (for example, orientation, training, and periodic refresher training) taken or planned to assure that , in the future, all individuals associated with NRC-licensed activities at Syncor facilities fulfill their responsibility to Syncor and to the NRC to conduct those activities, deal with the NRC, and maintain NRC records, in a forthright and candid manner and in accordance with the requirements of 10 CFR 30.9.

2. Your basis for having confidence in the integrity of those employees involved in the violations in Sections I and II of the Notice and your basis for having assurance that those individuals will not, in the future, willfully commit violations of NRC requirements

Item 1

A series of video tapes has been produced for training Syncor personnel. Two of these programs are presented to all personnel during their orientation and prior to their beginning work. These same two tapes are used for periodic refresher training. The titles of these videos are:

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (This tape instructs personnel in their obligation to fulfill their responsibilities to Syncor and to the NRC and also informs personnel of Syncor's obligation to them as employees.)

SEVEN RULES (These are rules of required practice when working in the restricted area)

An additional 6 videos are also available for training of specific procedures; they are:

AIR SAMPLING PROCEDURES

MINIMIZING EXTREMITY EXPOSURE

QUALITY CONTROL PROCEDURES

THYROID BIOASSAY PROCEDURES

I-131 CAPSULE COMPOUNDING PROCEDURE

IODINE-131 HANDLING

All Syncor locations are audited to insure that required training has been done and is documented. A copy of the items audited as they appear on the Quality and Regulatory audit form is attached.

Item 2

Only two individuals involved in the violations in Section 1 and II remain employed by Syncor. One employee, i.e. the individual (technologist) which Syncor's investigation revealed to the OI investigator, to our knowledge completed only one false record when directed to do so by the manager. This lady was not aware at the time that following the managers directive was falsifying records.

After the inspections and investigations by the NRC she became acutely aware of this type of violation and refused to add data to records which had not been completed. This refusal was at a time when the NRC investigator was present in the facility. She also volunteered the information to the Syncor regional manager during his investigation of the events causing the problems at this location. We are not aware that this individual has ever falsified another record. She has been a conscientious and loyal employee and has been totally trustworthy. Her commitment to regulatory compliance is all the better because of her experience in this incident.

The second employee, the pharmacist who admitted falsifying the alumina records, has become a valuable trusted employee. Even though your office maintains that she willfully falsified the alumina records we feel that was not the case. She had been trained in current policy and NRC requirements didactically. She was trained on the job by an individual who refused to change to current procedures. This unquestionably confused her and caused her to be undecided about what she should do. She was also aware of what seemed to be standard procedure by the QC technologist and the manager with respect to data entry on the quality control documentation.

		Y	N	N/A or Comment
III.	Health Physics Evaluation L. Vehicle Review			
3.	Vehicles placarded, driver qualifications current, supporting documentation sent to corporate, and emergency equipment available on vehicle when carrying DOT III shipments 49 CFR 172.504, DOT $ Fine SL III	—	—	———
4.	Security provided during loading of vehicles. Vehicles locked when unattended 10 CFR 20.207, SL III	—	—	———
5.	Accidents reported to corporate within 24 hours of occurrence. Documented on RS-23 10 CFR 20.403, SL V	—	—	———
6.	Tests results available on all DOT type 7A shipping containers that are used 49 CFR 173.461, DOT $ Fine, SL V	—	—	———
IV.	Training (discussions with staff, records review) 10 CFR 19.12, SL V			
A.	Knowledge of staff members of license conditions and NRC Part 19.12. Proper documentation on RS-60	—	—	———
B.	Knowledge of DOT requirements, emergency procedures and of the ALARA concept. Proper documentation RS-59	—	—	———
C.	Female employees instructed in Regulatory Guide 8.13. Training properly documented on RS-60	—	—	———
D.	Dispensers trained and tested in Moly/ alumina breakthrough testing. Training documented on RS-61a and proficiency documented on RS-61b 10 CFR 30.34 (g) and 35.204, SL V	—	—	———
E.	Initial employment and periodic retraining programs conducted and documented on RS-59 Item 8, 10 CFR 19.12, SL IV	—	—	———

	Y	N	N/A or Comment
IV. Training			
F. Training documentation available for personnel compounding I-131 therapy capsules	—	—	———
G. Personnel trained in the Bioassay procedure. Training documentation available	—	—	———
H. Personnel trained in Air Monitoring procedures. Training documentation available	—	—	———
I. Personnel trained in needleless WBC procedure. Training documentation available	—	—	———
J. Contamination Smear training documentation available	—	—	———
V. Regulatory (discussions with RSO)			
A. Pharmacy, State Law, SL IV			
1. Requested from the State Board of Pharmacy for advance approval of any remodeling, if appropriate	—	—	———
2. Advised the State Board of Pharmacy of any changes of Pharmacist in charge	—	—	———
3. Misadministrations reported to corporate RSO and documented on RS-58	—	—	———
4. Technician duties clearly defined, documented, and in compliance with State Pharmacy Laws. SL III	—	—	———
5. Used generators are not distributed for human use SL III	—	—	———
B. Personnel			
1. Authorized user and pharmacist on site when radiopharmaceuticals are dispensed, labeled, handled, and/or packaged. License Condition 11, 12, SL III	—	—	———
2. Customer license file current and complete CFR 30.41 (d), SL IV	—	—	———

We maintain that if she was willfully falsifying records she would not have volunteered that information to NRC personnel. If she had been more experienced and had received on the job training consistent with Syncor's policies she would not have completed the records after the fact. If she thought that she was willfully falsifying records after the July 1988 inspection she would not have continued to enter alumina data when the test was not done.

Since the NRC inspections and investigation she has been our watch dog with respect to regulatory compliance at this location. We are not aware that she falsified alumina records beyond the August dates referenced in the notice of violation letter or any other records. We are confident that based on her experiences during this incident that she will not in the future, willfully commit violations of NRC requirements.

This concludes our reply to the Notice of Violation.

Sincerely,

Gene McGrevin
President and C.E.O.

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

syncor®

September 17, 1990

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

Gentlemen:

This is our " **ANSWER TO NOTICE OF VIOLATION** "

Violations Assessed Civil Penalties

VIOLATION I

A. License Condition No. 19 requires, in part, that the licensee process radioactive material with reagent kits in accordance with the instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the reagent kit.

The brochure furnished by the manufacturer of the Tc-99m Medronate Reagent Kit used by the licensee on April 28, 1988 for compounding Tc-99m methylene diphosphonate (MDP) for bone imaging requires that sodium pertechnetate Tc-99m be slowly injected into the reaction vial.

Contrary to the above, on April 28, 1988, the licensee processed sodium pertechnetate Tc-99m with Tc-99m Medronate reagent kits in the preparation of Tc-99m MDP by injecting saline into the reaction vials supplied by the manufacturer, withdrawing the contents, adding the contents to a larger evacuated vial, and then adding sodium pertechnetate Tc-99m to the contents.

B. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed materials be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item K.2, that sodium pertechnetate elutions will be checked routinely for alumina breakthrough and that no eluate will be used if it exceeds 15 micrograms of alumina per milliliter of eluate.

Contrary to the above, sodium pertechnetate elutions were not routinely checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for preparation and dispensing of technetium-99m (Tc-99m) radiopharmaceuticals in at least the following examples,

1. On August 8, 1988 six elutions of sodium pertechnetate from the molybdenum-99/technetium-99m generator were made but five of the six elutions were not checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for the preparation and dispensing of technetium radiopharmaceuticals.

2. On August 9, 1988 eight elutions of sodium pertechnetate from the molybdenum-99/technetium-99m generator were made but seven of the eight elutions were not checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for the preparation and dispensing of radiopharmaceutical.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplement VI).

Cumulative Civil Penalty - $15,000 (assessed equally between the two violations).

Answer to I A

We request remission or mitigation of this civil penalty in accordance with the provisions of Section V.B. of 10 CFR Part 2, Appendix C (1988) ITEMS 2 and 3.

Very extensive corrective action was taken. The following is the sequence of corrective actions taken by Syncor:

1. April 29, 1988 a memo concerning misadministrations and apparent falsifications of records was sent to all Syncor locations.

2. The errors related to the misadministration identified on April 28, 1988 were investigated by the regional manager on April 29, 1988 and recommendations were made to place the individuals involved on probation.

3. A memo to all Central Region managers (9 locations) was sent on April 29, 1990 mandating corrective actions to insure product Q.C. was being done and being done correctly.

4. A memo was sent by the vice presidient of Quality and Rugulatory on April 29, 1988 to the Blue Ash manager requesting an internal investigation.

5. On June 1, 1988 a Health Physicist was sent to the Blue Ash location to train personnel.

6. A message was sent by the zone manager on May 6, 1988 to all region managers and senior management to implement corrective actions in all Syncor locations in the eastern zone.

7. After the inspection, and as a result of the confirmatory action letter, an amendment for the Blue Ash license was submitted to Region III by the Chairman of the Radiation Safety Committee on July 22, 1988. At the same time a memo was sent to the zone manager, regional manager and Blue Ash facility manager. This memo addressed additional corrective actions relative to Q.C. procedures, mandated that combining several product kits in a larger reaction vial be discontinued, directed that clear lead glass vial shields be used for all prepared products and informed the Blue Ash facility that they would be audited monthly. Reviewing our kit product sheets shows that using the large reaction vial for combining several product kits had been discontinued on August 5, 1988.

8. On July 22, 1988 a memo was sent by the Chairman of the Radiation Safety Committee indicating the disciplinary actions which would be taken for personnel making errors which contributed to misadministration.

9. On September 2, 1988 additional commitments were made to Region III which were implemented immediately and involved very extensive corrective actions.

10. A letter of confirmation was submitted to Region III dated September 7, 1988 by the Chairman of the Radiation Safety Committee for duel verification personnel.

11. On September 26, 1988 prior to the modifying order a letter was submitted amending all Region III licenses to include a quality control commitment for TC-99m labeled radiopharmaceuticals.

In addition to the above, an extensive investigation was undertaken by Syncor as a result of the modifying order and total compliance was achieved to the satisfaction of Region III which lifted the modifying the order.

We contend that the above actions taken by Syncor management represents extensive, corrective actions. We also feel that these actions were timely in nature in that the special safety inspection September 12th through the 15th, 1988 indicated that the Blue Ash facility was in full compliance with the confirmatory action letters. It was also in full compliance with the provisions of the regulations, the license and the conditions of its license application.

We also contend that the civil penalty leveled as a result of this violation should be mitigated on the basis of the prior good performance. Your inspection report dated October 25, 1988 documents that the Blue Ash pharmacy was inspected on August 22nd and 23rd, 1985 and no violations were identified. A previous inspection which identified violations was performed on June 5th and 6th, 1984. This 1984 inspection was requested by the Syncor Corporate Radiation Safety Officer in accordance with 10 CFR section 30.9. We had identified the violations which were subsequently issued and notified Region III the day we identified them.

We also feel very strongly that there are other reasons for not imposing this civil penalty.

1. A commitment was made by NRC officials that a citation for the violation involving failure to follow the manufacturer's instructions would not be issued. This commitment was made at the enforcement conference held at the Region III offices on April 27, 1990 and was referenced on Page 2 of the August 24, 1990 "Notice of Violation " letter. This commitment was also made in writing in the June 29, 1990 letter to Gene McGrevin which reported on the topics discussed at that enforcement conference.

2. In your Notice of Violation letter dated August 24, 1990 you state, "Both violations are especially significant in that failure to follow the manufacturer's instruction contributed in substantial part to an incident in which the final product of the formulation process was the wrong radio-pharmaceutical". You further say that this caused 14 diagnostic misadministrations.

The initial compounding of the MDP kit using the procedure stated in violation I.A. did not lead to any misadministrations. The first "super" kit was prepared and dispensed and all scans obtained from this material were acceptable. No complaints were received from any hospitals.

The misadministrations which occurred happened because the pharmacist did not add saline to the manufacturers reaction vials, and add the contents of several of these reaction vials to the larger vial. The misadministrations occurred because the pharmacist used the vial from the previously dispensed MDP "superkit" added pertechnetate solution (with no MDP reagent) and dispensed material from this vial.

It was human error that caused the fourteen misadministrations, not a variance from the package insert. In this instance the incident was caused by a human error which involved the reuse of an empty vial which had already been used. The pharmacist did not even go through the procedure of injecting saline into the manufacturers vials and adding them to the larger vial. The error here was failure to follow any instructions. It is difficult to imagine that an error of this type is willful.

Answer to I B

The reason for total mitigation of this fine:
The violation is denied. See "Reply to Notice of Violation".

VIOLATION II.

10 CFR 30.9(a) requires information provided to the Commission by a licensee or information required by the Commission's regulations or license conditions be complete and accurate in all material respects.

License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed material be used in accordance with statements, representations and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 provides in Item 17, Appendix I that records will be kept of daily surveys of elution and preparation areas.

Contrary to the above, on at least one occasion in May or June 1988, the record kept of the daily survey of the licensee's elution and preparation areas was not accurate in that survey readings were falsified by a licensee employee at the direction of a licensee management official.

This is a Severity Level III violation (Supplement VII).

Civil Penalty - $5,000.

Answer to violation II.

We request remission or mitigation of this civil penalty in accordance with the provisions of Section V.B. of 10 CFR Part 2, Appendix C (1988) Item 2 and 3 .

See response to violation I.A. Item 1,5,6,7,9,10,11. which are hereby incorporated by reference.

In addition the individual referenced in this violation refused to back fit records when requests to do so by the manager a second time and was in compliance (self-disciplined compliance) prior to the July routine inspection. The manager and RSO involved in this incident was severely disciplined and subsequently resigned.

We also request mitigation of this penalty on the basis that Syncor personnel identified the survey record falsification and reported this to the NRC investigator.

Prior Good Performances:

We also request that all penalties be mitigated on the basis of prior good performances both at the Blue Ash facility and throughout the Syncor facilities nationwide.

NRC has stated that much of the cause for issuing the civil penalties is based on the premise that variations from the instructions in preparing Tc-99m tagged kit products have led to misadministrations. We agree that the "super" kit concept would, or could, lead to MORE misadministrations if a human error were made in preparing this kit. We do not agree that variation from the package insert in preparing the kit will in itself cause misadministrations.

We also know, based on figures released by the NRC, there is one misadministration per eight thousand three hundred and thirty three (8,333) doses injected in the nuclear medicine community annually. Four hundred of these misadministrations occur in NRC states and 800 misadministrations occur in Agreement States. Annually, Syncor pharmacists are responsible for one misadministration in every fifty thousand doses dispensed (50,000). Included in this statistic are errors associated with the preparation of "Super" kits.

Syncor, at the suggestion of the NRC, has retained a consultant in human factors engineering as part of our long range strategy. To better understand Syncor's commitment to regulatory compliance, we included excerpts from the closing remarks at the Enforcement Conference in Region III by Gene McGrevin, President and Chairman of the Radiation Safety Committee at Syncor, see attached Exhibit A.

Syncor feels that we have made a strong argument for mitigation of the civil penalties assessed and that present management commitment to quality and regulatory matters must be taken into account when considering this action.

In summary please consider the following:

1. Syncor's past good record
2. We have identified our own problems and have brought them to the attention of the Nuclear Regulatory Commission
3. Timely action
4. Strong and extensive corrective steps which are taken when problems are identified
5. Increased training programs
6. A strengthened future commitment to Quality and Regulatory

In accordance with the factors addressed in Section V.B. of 10 CFR Part 2, Appendix C (1988) as summarized above, and denial of Violation I B., we request mitigation of the civil penalties issued in this " Notice of Violation."

Sincerely,

Gene McGrevin
President & C.E.O.

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

E

X

H

B

I

T

"A"

Exhibit A

Gene McGrevin's Closing Remarks From the Enforcement Conference

"I joined Syncor on February 1, 1989, as President and Chief Executive Officer and a member of the Board of Directors. I have spent the past 20 years managing various health care companies, including 8 years at Kimberly-Clark corporation and 7 years at Johnson & Johnson. In fact my personal philosophy on customer service and quality was formulated and significantly influenced by my Johnson & Johnson training. As a result of this training and experience, the management team at Syncor developed a strategy and mission statement consistent with our dedication to serve the customer and provide a quality product."

"As part of our long-range strategy, each department developed a strategy and/or mission statement. During the budget process, these statements were used to identify and allocate funding. I am pleased to announce that the budget of the Quality and Regulatory Department was increased by 20%. This was done to ensure adequate resources to achieve its mission."

"As you can see, we have made the Quality and Regulatory Department the customer's representative within Syncor. We have also given this group the authority and responsibility for compliance. The Quality and Regulatory Department reports to a senior officer of the corporation. This officer reports to me. In addition, I am also the Chairman of the Radiation Safety Committee."

"Syncor desires to be recognized as an environmentally responsible company. This can only be accomplished by complying with all local, state and federal rules and regulations. In other words, the management of Syncor is dedicated to compliance and quality in all phases of our operation."

"Let me list some of the accomplishments we have made in our brief management tenure."

"First, we introduced a program entitled the "Challenge of Change". This program created a positive atmosphere regarding change within the company. The change was directed toward excellence and customer service."

"We then created a more workable management structure."

"We are creating a team environment in which the team is only as successful as its weakest link. As part of this, incentive programs are based on team performance. A portion of the bonus hinges on regulatory compliance. (All individuals within a location are eligible to receive a bonus.)"

"We have created an ESSOP (Employee Saving and Stock Ownership Plan). This program will create both the pride and responsibility associated with ownership. This will link all of the local teams (pharmacies) together."

"We have revised the " Compliance Audit Form" so that it once again references the regulatory document as well as the regulation with-in the document. We have assigned severity levels to each item of non-compliance so that individuals within the location can identify those items which could lead to escalated enforcement actions."

"During the past year, we have implemented additional training programs and produced eight (8) regulatory training tapes."

"We have introduced one major change in our audit program. When/if an auditor identifies a serious violation and believes individuals within the pharmacy are not capable of coping with the problem, it is his/her responsibility to remain at the facility. The auditor has the authority to make any corrections he/she deems necessary to protect the environment, the worker and/or the public."

"Syncor has hired an industrial engineer to work on pharmacy design and work flow patterns. We are projecting that 14 Syncor locations will be moved in the next fiscal year. This is being done in an effort to upgrade the quality of our locations."

"We have established a committee to begin working on a "model pharmacy" concept. The model pharmacy will be developed by a panel of experts and will use human factor engineering to address components of the operation which could contribute to human error. This committee is mandated by management to standardize all phases of the Medical Service Group (MSG) operations (see Appendix J)."

"These are only a few of the changes management has introduced, and we expect positive results. An example of the results is the inspection results for the first quarter of 1990. Nine pharmacies were inspected by the NRC. Six of the pharmacies received no violations."

"One of the reasons we are here is because of the misadministrations which occurred at the Blue Ash facility. While the ultimate goal of Syncor is zero misadministrations, I would like to present the following information. Portions of the data are taken from a study done by the NRC while preparing for the proposed regulation on quality control in Part 35. The rest of the information was compiled by our Q & R staff. This group monitors errors which lead to misadministration at all of Syncor's locations."

DIAGNOSTIC MISADMINISTRATIONS

NRC data indicates that 400 diagnostic misadministrations occur per year.

Since there are twice as many agreement state licenses as there are NRC licenses, we can project that an additional 800 misadministrations occur per year. (A total of 1200 diagnostic misadministrations per year.)

Syncor errors leading to possible misadministration were 80 for 1989.

NRC data indicates that 10,000,000 nuclear medicine diagnostic procedures are performed per year by all licensees.

Syncor services 40% of the nuclear medicine community by preparing and dispensing 4,000,000 doses per year.

From the above data, we can make the following assumptions:

NATIONWIDE -- 1 MISADMINISTRATION PER 8,333 PROCEDURES

SYNCOR -- PREPARES 40% OF DIAGNOSTIC DOSES

ACCOUNTS FOR 6.7% OF DIAGNOSTIC DOSAGE ERRORS

1 ERROR LEADING TO A MISADMINISTRATION PER 50,000 PROCEDURES

RADIOPHARMACEUTICAL THERAPY MISADMINISTRATION

NRC data indicates that 30 to 45 therapy misadministrations have occurred in the last five years, or 6 to 9 per year.

Syncor's involvement created a portion of the problem in one.

From this data, we can calculate the following.

IN THE LAST FIVE YEARS

SYNCOR -- PREPARED 40% OF RADIOPHARMACEUTICAL THERAPY DOSES

INVOLVED IN A PORTION OF PROBLEM IN ONE THERAPY ERROR

INVOLVED IN LESS THAN 3% OF THE ERRORS LEADING TO A THERAPY MISADMINISTRATION

In conclusion, I will not tolerate individuals who falsify records. When identified, those individuals will be dealt with in accordance with company policies and procedures."

"While I believe the data presented proves our past record is excellent, especially when compared to the industry, Syncor's overall objective is zero misadministrations. We will never be satisfied until that occurs."

****

E

X

H

B

I

T

"B"

****

TABLE OF CONTENTS

syncor™

The National Pharmaceutical Service Network

INCIDENT/COMPLAINT (I/C) REPORT

Date of this report 4/29/88

Person filling out this report William McHugh

DATE OF I/C 4/28/88

Institution reporting I/C Bethesda North Hospital/Cincinnati, (Phone # Bethesdan. 513-745-1155)

Description of the I/C Tom Papke called me to report 5 patients showed scintigrams detailing only thyroid, salivary glands and stomach. Doses administered labeled as MDP. Original QC performed by Laurie Loomis indicated 95.7% tag. Six hours later QC performed by Todd Cole indicate 10% tag. No waste MDP vials could be located.

Action taken to correct the I/C Conclusion - misadministration of Tc04. Tom Papke was notified to give Michelle Loos the names of patients and referring Doctors involved so that we could report it.

Measures taken to prevent re-occurence See memo RE quality assurance dated 4/29/88. Laurie Loomis and Carla Grider are to be placed on six months probation. Carla was RPh in charge.

Final notes on assessment RX#s 233837-39, 834, 840, This situation will also cost us $1800.00 in credits to Bethesda North. We are assessed this as loss revenue to Bethesda North.

One of three things happened with Laurie Loomis. She either:

1. Fabricated Results
2. Counted wrong portion of chromatography strip as pertaining to tagged product. (origin not counted but solvent front identified as the origin.

Syncor International Corporation
Medical Services Group
100 North Euclid, Suite 900
St. Louis, Missouri 63108
(314) 367-9300

3. Spotted chromatography strip with a previously tested syringe and identified it as MDP.

Signature of
reporting person

William C. McCarthy

cc Michelle Boos
Jim Stone
Richard Keesee
Jack Coffey
Bob McClintock

WCM/jh

syncor

The National Pharmaceutical Service Network

TO: Region 20 Managers

FROM: Bill McHugh WCM

DATE: April 29, 1988

RE: Quality Assurance of Radiopharmaceuticals

As a result of numerous misadministrations of radiopharmaceuticals which should have been caught if quality control was performed or performed properly, a number of items are to be implemented immediately:

1. All QC technicians and those doing QC are to be evaluated as to competency in the performance of this task. Use RS-59 for the documentation.

2. On a random basis the pharmacist is to test the QC technician's compliance in the performance of his or her responsibility. Pertechnetate is to be substituted and represented as a tagged radiopharmaceutical to the technician. The technician will not be informed that this is a bogus syringe. He is being tested on his or her ability to identify a poorly tagged product and to convey this fact to the pharmacist and he or she are being tested as to whether the QC procedure is being performed in the first place.

3. QC is to be run on all products prior to their departure from the pharmacy.

4. Set up a method of dual verification of all kit preparation with a sign-off sheet.

Syncor International Corporation
Medical Services Group
100 North Euclid, Suite 900
St. Louis, Missouri 63108
(314) 367-9300

5. All dose drawers are to be made aware that anytime the observed dose activity doesn't correspond with the activity printed on the prescription for the volume specified, he or she is to question the product and verify it or have it verified. This is to be a dual verification also. [illegible]-59 to document this training.

A meeting should be called informing those involved in QC of the importance of their responsibility and the aforementioned directives. They should also be informed that failure in this area will result in a reprimand and possible grounds for termination.

Please notify me in writing with the date of implementation of these procedures.

cc Bob Irwin
Jim Stone
Jack Coffey
Bob McClintock
Richard Keesee

WCM/jh

JLC 80429 C

MEMORANDUM

To: Pharmacy Service Center Personnel

From: Monty Fu, Radiation Safety Committee Chairman

Date: April 29, 1988

Re: Misadministrations, QC, and Records

Misadministrations

The number of recent misadministrations is of great concern to the Radiation Safety Committee and we believe should be of concern to all personnel involved. We realize we are all human and will undoubtedly make an occasional unpreventable mistake. The human error type mistakes are of concern because no one likes to make a mistake which results in a patient receiving unnecessary radiation exposure. Of greater concern are the preventable misadministrations which result from not following established procedures or the lack of a required verification in the procedure. These misadministrations are contrary to the operating philosophy of Syncor and are a threat to our customer service commitment. Everyone must commit themselves to zero preventable misadministrations.

The regulatory agencies are considering enforcement options for dealing with misadministrations by nuclear pharmacies. Our position in the field makes us the target for the most scrutiny. Syncor's short term performance can impact how the enforcement options are developed. Please do your part in assuring our company maintains a positive leadership role in this area.

Quality Control

Again, I would like to clearly state the Quality Control policy of Syncor. QUALITY CONTROL WILL BE PERFORMED ON ALL PRODUCTS BEFORE THEY LEAVE THE SYNCOR FACILITY.

Our commitment to our customers to provide the best service cannot include inferior products. Quality control is the final check we perform to assure the customer of the best quality product from Syncor. There will be no exceptions to this requirement. This will also serve as notice to all supervisory personnel to take disciplinary actions when these important standards of our company are violated.

Records

At our April 21, 1988 Radiation Safety Committee meeting, the members discussed the seriousness of an audit finding showing records which were routinely falsified. This practice is unacceptable. It is imperative all personnel perform and document tests, measurements, etc. as required. If for some reason a test is not done, the record should remain blank. This blank should be identified as soon as discovered and initialed by the center's RSO during the monthly audit. In addition, corrective actions to prevent recurrence should be documented.

It is necessary for each of you to review your present operation. If falsification of records ever occurs, take appropriate actions and immediately notify your regional manager. Full compliance with this requirement is essential.

Your prompt attention to these important matters is appreciated.

cc: Regional Managers
Zone Directors
Management Team
Radiation Safety Committee
Health Physics Group

Start of Item 13.

Message.
Subject: Misadministration in Blue Ash
Sender. Richard KEESEE / SYNCOR/00
FROM: Richard KEESEE / SYNCOR/00

Dated: 04/29/88 at 1636.

Contents: 2.

Part 1.

FROM: Richard KEESEE / SYNCOR/00

TO: Bob IRWIN / SYNCOR/00

Part 2.

We had 13 misadministrations in Blue Ash on Thursday, April 28th.

Five of the misadministrations went to Bethesda North Hospital. (The syringes actually contained Sodium Pertechnetate.)

Michelle Loos was off on Thursday and the technician was told that it was a Q.C. problem. (Today Michelle confirmed that it was a misadministration.)

This individual called in on the 800 line since he had a similar problem on April 15th (4 doses) and was told that it was a Q.C. problem.

The customer also called Bill McHugh and the N.R.C.

Michelle promised me that she would look at the scans from the 15th on Monday to see if it was pertechnetate instead of MDP.

End of Item 13.

RS-59 (6/9/86)

IN-SERVICE ATTENDANCE RECORD

Lecture Title: Health Physics Inservice

Date: 6/1/88

Instructor: Marcia Chester

Attended By The Following:

Name (Print)	Signature	Position
Laurie Loomis	[signature]	Tech.

Topics Covered:

Reviewed QC procedure - will be using the QC manual exclusively
Random room wipes should be performed in the mornings (areas used by the pharmacist)

RS-59 (6/9/86)

IN-SERVICE ATTENDANCE RECORD

Lecture Title: Health Physics Inservice

Date: ~~6/~~ 5/31 - 6/1 1988

Instructor: Marcia Chester

Attended By The Following:

Name (Print)	Signature	Position
Todd Cole		Todd Cole

Topics Covered:

Efficiencies, LLD, MDA, bioassay, air monitoring, QC, Cs-137 consistency

RS-59 (6/9/86)

IN-SERVICE ATTENDANCE RECORD

Lecture Title: Health Physics Inservice

Date: 6/1/88

Instructor: Marcia Chastain

Attended By The Following:

Name (Print)	Signature	Position
Carla Grider	Carla Grider	Pharmacist

Topics Covered:

air monitoring
bioassay

syncor

RS-59 (6/9/86)

IN-SERVICE ATTENDANCE RECORD

Lecture Title: Health Physics Inservice

Date: 5/31 - 6/1 1988

Instructor: Marcia Chester

Attended By The Following:

Name (Print)	Signature	Position
Brenda Weaver	Brenda Weaver	
Michelle Fortner	Michelle Fortner	
BRENDA		

Topics Covered:

responsibilities as to watching over other drivers - correcting any action needed. For example, reminding drivers to wear film badges, buttoned labcoats, making sure LQR policy is properly done

Start of Item 18.

Message. Dated: 05/06/88 at 0603.
Subject: Misadministrations
Sender: Jim STONE / MCI/GW Contents: 3.
TO: Richard KEESEE / SYNCOR/00

Part 1.

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

Part 2.

MESSAGE HEADER.

Part 3.

Yesterday I sent a memo concerning misadministrations. I am told that it did not transmit correctly. I have tried to correct the error and send it to you again. Sorry for the problem.

Jim

M E M O R A N D U M

TO: Jack Coffey

FROM: Jim Stone

DATE: May 5, 1988

RE: MISADMINISTRATION

As we discussed on the phone recently I would like to make some additions and suggestions to Bill McHugh's recent memo to Region 20 managers. Since I will send a copy of this memo to the Zone 2 Regional Managers, I am restating Bill's ideas as well.

(1) All QC technicians and those doing QC should be evaluated as to their competency in the performance of this task. RS-59 should be used for documentation.

(2) On a random basis the pharmacist is to test the QC technician's compliance in the performance of his or her responsibility. Pertechnetate is to be substituted and represented as a tagged radiopharmaceutical to the technician. The technician will not be informed that he/she is being tested. He/She is being tested on his/her ability to identify a poorly tagged product and to convey this fact to the pharmacist. This also serves as a method to assure that QC is being done. The result of missing a test syringe is to retrain and document for the first incident. A written warning and the progressive disciplinary chain is be followed thereafter.

(3) All QC is to be run on ALL products prior to their departure from the pharmacy.

(4) A method of dual verification of all kit preps should become standard operating procedure. This method should be a standard sign off sheet that is consistent across the country without exception. Your understanding is that G. Redmore is in the process of polling Region 23 managers on their methods of accomplishing this. A composite of the best of Region 23 submissions along with anyone else who would like to have their form considered should be adopted as policy.

(5) All dose drawers are to be made aware that anytime the observed dose activity does not correspond with the activity printed on the prescription for the volume specified, he/she is to question the product and verify it or have it verified.

(6) I would also advise dual verification on multidose vials of ANYTHING. Our problem has not been with single dose misadministrations as much as it has been with multidose misfilling with numerous patients involved.

(7) Next day set up should be dual verified by two members of the shift and signed off. We might also consider having the set up verified the following morning as well. Thus, the scripts would be looked at three times prior to filling.
page 2

(8) It is current policy that two (2) signatures are required if a technician fills a syringe. This should be stressed again.

(9) Presently there are no company policies which provide actions to be taken when a Syncor employee is involved in a misadministration. I would suggest something along the following lines:

First Occurrence - written warning to be issued along with a 90 day probation.
A second occurrence within 90 days could result in termination.
Other Occurrences - a total of three (3) misadministrations in a two year period could also result in termination.
Employees Involved - if the misadministration is a result of set up or mistyping, the involved employee is given a written warning with the same disciplinary procedure as above.

I am going to have the above become Zone policy, if we Radiation Safety Committee does not request that this program or a hybrid become company policy. As a company, we cannot afford dual verification by AUTHORIZED USERS, however we can now in most cases with schedule rearrangement accomplish dual verification with TRAINED INDIVIDUALS. I will not implement any changes until such time as a decision is reached by the Radiation Safety Committee.

cc: Zone 2 Regional Managers
Bob Irwin
Richard Keesee
Greg Hiatt

End of Item 18.