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OFFICE OF THE INSPECTOR GENERAL
REPORT OF INVESTIGATION



ALLEGED HARASSMENT BY NRC REGION I STAFF AND ABSENCE OF
DUE PROESS WITH RESPECT TO THE CAMEO DIAGNOSTIC CENTRE

CASE NO. 93-72H

[REDACTED] 2/1/94
SPECIAL AGENT DATE

[REDACTED] 2/1/94
TEAM LEADER DATE

Les J. Norton 2/3/94
ASSISTANT INSPECTOR DATE
GENERAL FOR INVESTIGATIONS

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STATUTES AND REGULATIONS

10 CFR Part 0.735-49a

SUBJECTS

[REDACTED]

U.S. Nuclear Regulatory Commission

[REDACTED]

U.S. Nuclear Regulatory Commission

[REDACTED]

U.S. Nuclear Regulatory Commission

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SYNOPSIS

In a May 18, 1993, memorandum to the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), James LIEBERMAN, Director, Office of Enforcement, NRC, forwarded correspondence from Cameo Diagnostic Centre (CAMEO) that suggested improper actions by NRC staff. CAMEO possesses a Byproduct Material License pursuant to 10 CFR Part 35 for imaging and localization procedures.

In an interview with OIG, [REDACTED] CAMEO, alleged that the NRC has harassed [REDACTED] and has taken actions against [REDACTED] based on personal animus. [REDACTED] asserted that, during the controversy surrounding [REDACTED] license renewal and change of address, the NRC deprived [REDACTED] of adequate notice and denied [REDACTED] due process when the NRC shut down [REDACTED] business by preventing suppliers from shipping NRC licensed material to CAMEO.

This OIG investigation determined that the actions taken by NRC staff with respect to [REDACTED] and [REDACTED] NRC license were in accordance with the provisions of 10 CFR. This investigation did not substantiate [REDACTED] allegations that NRC staff acted inappropriately with respect to the handling of [REDACTED] NRC license or that NRC staff exhibited a personal animus against [REDACTED].

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BASIS

This Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), investigation was initiated in response to information provided by James LIEBERMAN, Director, Office of Enforcement. In a May 18, 1993, memorandum to OIG, LIEBERMAN referred to correspondence received from Cameo Diagnostic Centre (CAMEO), a Region I (RI) NRC licensee, that suggested improper action by NRC staff. CAMEO possesses a Byproduct Material License pursuant to 10 CFR Part 35 for imaging and localization procedures.

In an interview with OIG, [REDACTED] CAMEO, alleged that the NRC has harassed [REDACTED] and taken actions against [REDACTED] based on personal animus.

[REDACTED] also raised additional concerns that were not addressed in this report as they fall outside OIG purview. [REDACTED] criticized the NRC's escalation of a civil penalty for violations surrounding CAMEO's willful use of licensed material at an unauthorized location and the willful failure to inform the NRC of such use.

[REDACTED] also alleged that the NRC failed to provide a full disclosure of records pertaining to [REDACTED] Freedom of Information Act request. In addition, [REDACTED] questioned the results of an inspection conducted by RI in which several regulatory violations were identified.

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DETAILS

OIG interviewed [REDACTED] Cameo Diagnostic Centre (CAMEO) to obtain information in support of [REDACTED] allegations that the NRC has harassed [REDACTED] and taken actions against [REDACTED] based on personal animus.

[REDACTED] said CAMEO was opened around 1987 as both a diagnostic and therapeutic center. Soon thereafter, CAMEO became only a diagnostic center. CAMEO was issued a Byproduct Material License (No. 20-27908-01) by the NRC pursuant to 10 CFR Part 35 on January 30, 1987. The license authorized the use of certain byproduct materials for imaging and localization procedures at Suite A, 110 Maple Street, Springfield, MA.

According to [REDACTED] the NRC licensed procedure performed at CAMEO involves the injection of small amounts of technetium-99m (Tc-99m) into a patient to determine areas of the patient's body where cancer may have developed. Because the half-life of Tc-99m is six hours, [REDACTED] said it poses little risk to the public health and safety. Due to this short half-life, CAMEO receives Tc-99m doses from a pharmacy every morning at 6 a.m. for patients who will be treated that day. CAMEO deals almost exclusively with patients with possible bone cancer.

[REDACTED] said [REDACTED] submitted an application for license renewal, along with a fee of \$1,000, to the NRC on January 28, 1992, as [REDACTED] license was due to expire on February 28, 1992. This application contained no changes to the original NRC license. At some point during the Summer of 1992, [REDACTED] said [REDACTED] Medical Inspection Section, Division of Radiation Safety and Safeguards (DRSS), Region I (RI), rejected CAMEO's renewal application and requested more information from [REDACTED]. According to [REDACTED] this additional information was not necessary because CAMEO only performed diagnostic procedures using TC-99m with a six hour half-life.

[REDACTED] recalled that [REDACTED] Nuclear Materials Safety Branch, DRSS, RI, informed [REDACTED] by telephone that [REDACTED] problems with the license renewal should have been handled in a different way because of the nature of the work done by CAMEO.

[REDACTED] said [REDACTED] visited RI on October 21, 1992, to provide a response to NRC identified deficiencies in [REDACTED] license renewal application. It was at this meeting that [REDACTED] said [REDACTED] advised RI officials [REDACTED] and [REDACTED] of [REDACTED] plans to move CAMEO from 110 Maple Street to 155 Maple Street.

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Subsequent to the October 21, 1992 meeting, [redacted] said [redacted] was informed by RI that the NRC required that [redacted] submit an amendment to [redacted] current license, reflecting the new location, along with another \$1,000 fee. Because CAMEO still had its license renewal application pending, [redacted] requested that [redacted] be allowed to incorporate the license amendment as an addendum to [redacted] license renewal application in order to save the \$1,000 amendment fee. [redacted] stated [redacted] received no answer from the NRC regarding this request.

On November 2, 1992, [redacted] said CAMEO shut down operations and moved from 110 Maple Street to 155 Maple Street, Springfield, MA. On November 3, 1992, CAMEO commenced operations at the new location. On November 11, 1992, [redacted] telephoned [redacted] and left a voice mail message indicating that [redacted] had made the move and was very busy. [redacted] informed [redacted] that as soon as things returned to normal [redacted] would contact [redacted] again and provide [redacted] with the information [redacted] required.

On November 12, 1992, [redacted] said [redacted] telephoned [redacted] and advised [redacted] that [redacted] needed to submit an application for a license amendment. [redacted] also informed [redacted] that CAMEO could not use any isotopes at the new location until [redacted] submitted a license amendment, along with a \$1,000 fee, that reflected the change of address. According to [redacted] this conversation was documented in a letter from RI.

On November 17, 1992, [redacted] said [redacted] advised RI in writing of [redacted] request to incorporate the new address for CAMEO into [redacted] application for license renewal. During this period, [redacted] said [redacted] was continually communicating with RI regarding this request and RI was aware that CAMEO had moved and was conducting business as normal. [redacted] thought RI was deciding on [redacted] request to incorporate the move into the license renewal.

According to [redacted] the daily shipment of Tc-99m did not arrive at CAMEO on December 11, 1992. [redacted] said [redacted] telephoned Syncor International Corporation (SYNCOR), the supplier, and [redacted] was told the NRC had contacted them and threatened them by suggesting that SYNCOR not ship further doses of Tc-99m to CAMEO. Because there were no doses to administer to the patients, CAMEO was forced to cease operation. [redacted] commented that CAMEO had appointments set up weeks in advance for patients to undergo diagnostic procedures to detect bone cancer. Because of the action by the NRC, CAMEO was forced to contact these patients to cancel their appointments. [redacted] opined that the action by the NRC was unjustified and unnecessarily placed the health of [redacted] patients at risk.

[redacted] said that because [redacted] received no advance notice of the NRC action to close [redacted] business, [redacted] telephoned [redacted] on December 11, 1992 to ascertain what was happening. [redacted] told [redacted] to submit an amendment application

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along with a \$1,000 fee. [REDACTED] said [REDACTED] threatened that [REDACTED] was going to send [REDACTED] a Confirmatory Action Letter (CAL) with an Order to cease operation of CAMEO. [REDACTED] also informed [REDACTED] that it would take about 24 hours for the NRC to review and act upon the application for amendment after it was received.

On December 11, 1992, [REDACTED] sent RI, by Federal Express, the application for amendment reflecting the new location and the \$1,000 fee.

[REDACTED] said [REDACTED] received a Demand for Information (DEMAND) from the NRC on December 17, 1992. [REDACTED] considered the DEMAND as being the first formal notice that the NRC intended to take action if an application for a license amendment indicating the change of address was not submitted. Previous to this notification, [REDACTED] thought the NRC was deliberating over [REDACTED] request to incorporate the license renewal and change of address into one action. On December 18, 1992, [REDACTED] faxed to the NRC [REDACTED] response to questions asked in the DEMAND.

[REDACTED] indicated that RI conducted an inspection of CAMEO on December 29, 1992. Following this inspection, RI cited CAMEO for violating several regulatory requirements, including CAMEO's failure to have an appropriate Radiation Safety Officer (RSO). According to [REDACTED] the NRC had always accepted [REDACTED] as the RSO. In order to satisfy this NRC requirement, [REDACTED] submitted the name of [REDACTED] for the University of Massachusetts, to Region I for approval. [REDACTED] said [REDACTED] previously agreed to be the RSO for CAMEO, but later withdrew [REDACTED] name from consideration. According to [REDACTED] [REDACTED] had been contacted by [REDACTED] and that [REDACTED] intimidated [REDACTED] into withdrawing [REDACTED] name.

The second name submitted by [REDACTED] for RSO on his NRC license was [REDACTED] for the Massachusetts Institute of Technology (MIT) and a certified health physicist. [REDACTED] stated that [REDACTED] was found to be unacceptable by [REDACTED]. [REDACTED] was never informed of the reasons why neither [REDACTED] nor [REDACTED] were accepted by the NRC. Finally, [REDACTED] submitted the name of [REDACTED] as RSO. [REDACTED] was found to be acceptable by the NRC. [REDACTED] did not know why the NRC considered [REDACTED] to be more qualified for the position than [REDACTED] or [REDACTED].

[REDACTED] asserted that the NRC's actions to close [REDACTED] business during the controversy over the license renewal and [REDACTED] change of address, deprived [REDACTED] of adequate notice and denied [REDACTED] due process (Exhibit 1).

[REDACTED] DRSS, RI, and [REDACTED] DRSS, RI, informed OIG that they first learned of [REDACTED] plans to change the

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location of [REDACTED] NRC licensed business during an October 21, 1992, meeting with [REDACTED] at RI. [REDACTED] was visiting Region I to discuss [REDACTED] license renewal request and its deficiencies. [REDACTED] said [REDACTED] complained that NRC regulations are unfair and unnecessary for a licensee who only uses Tc-99m. [REDACTED] said [REDACTED] told [REDACTED] could petition the NRC to change its rules if [REDACTED] did not like them or if [REDACTED] thought they were unfair.

[REDACTED] and [REDACTED] said that during the October 21, 1992, meeting, [REDACTED] was advised not to use licensed material at the new location until [REDACTED] either obtained a license amendment or until [REDACTED] license renewal application incorporating the change of location had been processed and approved (Exhibits 2 & 3).

[REDACTED] and [REDACTED] also said [REDACTED] was told that in order to obtain NRC authorization to use licensed material at the new location, [REDACTED] must either apply for and receive a license amendment or include the change of location in [REDACTED] license renewal request (Exhibits 4 & 5).

[REDACTED] and [REDACTED] said [REDACTED] insisted that the change of location be processed with [REDACTED] license renewal so [REDACTED] could avoid paying the license amendment fee. According to [REDACTED] [REDACTED] has always been concerned about the fees charged by the NRC for inspections and licenses (Exhibits 2-5).

[REDACTED] and [REDACTED] told OIG that [REDACTED] was also informed that [REDACTED] license renewal would take an extended period of time to be processed because the exemptions [REDACTED] had previously requested were being reviewed by the Office of Nuclear Material Safety and Safeguards (NMSS) at NRC Headquarters. [REDACTED] and [REDACTED] said [REDACTED] was advised not to use licensed material at [REDACTED] new location until [REDACTED] license renewal, reflecting the change of location, had been approved (Exhibits 2-4).

[REDACTED] said [REDACTED] staff also informed [REDACTED] on several occasions that a license amendment could be processed quickly while [REDACTED] license renewal would take longer because of the exemptions. Even after being advised of this, [REDACTED] said [REDACTED] opted to have the change of location incorporated into [REDACTED] license renewal because [REDACTED] did not want to pay the amendment fee. According to [REDACTED] [REDACTED] DRSS, RI, [REDACTED] was told that to quicken the renewal process [REDACTED] could delete the exemptions, however, [REDACTED] was unwilling to do so (Exhibits 5 & 6).

[REDACTED] and [REDACTED] said the length of time taken to complete [REDACTED] license renewal was not out of the ordinary. [REDACTED] explained that in January 1992 when [REDACTED] submitted [REDACTED] license renewal request, it was not unusual for a renewal application to take up to one year to be processed.

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[redacted] said that [redacted] was issued a "deemed timely filed" letter in February 1992 which allowed [redacted] to continue operation under the conditions of [redacted] previous NRC license.

[redacted] and [redacted] said the processing of [redacted]'s license renewal request was complicated by [redacted] failure to provide the NRC with sufficient and timely information in response to deficiency letters sent in April and July 1992 and because of [redacted] request to be exempt from several NRC regulations. Based on [redacted]'s failure to respond to these deficiency letters, the NRC issued a "threat to abandon" letter to [redacted] on August 28, 1992. This letter advised [redacted] that if [redacted] did not respond to NRC identified deficiencies within 30 days, the NRC could take action to abandon the license renewal process until the matter is resolved. [redacted] said [redacted] received [redacted]'s response to this request in a letter dated September 23, 1992 (Exhibits 4 & 5).

[redacted] and [redacted] recalled that [redacted] called [redacted] on November 12, 1992, and left a message on [redacted] voice mail indicating that [redacted] had moved and that [redacted] would be late in responding to the deficiency letter pertaining to [redacted] license renewal. [redacted] did not inform [redacted] in this message that [redacted] was using licensed material at the new location. [redacted] and [redacted] returned the call and specifically asked [redacted] if [redacted] was using material at the new location and [redacted] said that [redacted] was not. [redacted] said [redacted] and [redacted] again advised [redacted] not to use NRC licensed material at the new location until [redacted] either obtained a license amendment or until [redacted] license renewal reflecting the change of location was processed. [redacted] said [redacted] acknowledged that [redacted] was not authorized to use NRC licensed material at the new address. [redacted] and [redacted] said a letter was sent to [redacted] on November 13, 1992, documenting this conversation (Exhibits 2 & 3).

[redacted] and [redacted] suspected that [redacted] might be using licensed materials at the new address, in spite of [redacted] denials. [redacted] said [redacted] could not understand how [redacted] could stay in business if [redacted] was not operating, and [redacted] needed materials to operate. According to [redacted] however, because [redacted] also performed work at CAMEO using non-NRC regulated material, [redacted] believed it was possible that [redacted] could resume business at the new location without using NRC licensed material and without violating NRC regulations (Exhibits 2 & 4).

[redacted] said [redacted] asked [redacted] DRSS, RI, to contact pharmacies in the vicinity of CAMEO to determine if [redacted] was receiving licensed material at the new address. [redacted] said [redacted] spoke with [redacted] of SYNCOR and was informed that [redacted] had been receiving shipments of Tc-99m at [redacted] new address since November 3, 1992. [redacted] said [redacted] referred this information to [redacted] and [redacted] (Exhibits 4 & 7).

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██████████ said SYNCOR was advised by letter on December 11, 1992, that CAMEO was not authorized to receive licensed material at the new location. ██████████ explained that 10 CFR Part 30.41 prohibits the transfer of byproduct materials to a location not specified on an NRC license. As an aside, ██████████ said that following an NRC inspection of SYNCOR in November 1993, SYNCOR was cited for violating NRC regulations by shipping licensed material to an address not listed on CAMEO's specific license (Exhibit 4).

██████████ said ██████████ asked ██████████ during a telephone conversation on December 11, 1992, if ██████████ had been using licensed material at the new location without NRC authorization and ██████████ acknowledged that ██████████ had. ██████████ then asked ██████████ to voluntarily agree to stop using this material. ██████████ refused. ██████████ told ██████████ that ██████████ couldn't stop because ██████████ would lose business. ██████████ said ██████████ advised ██████████ on this occasion to submit an license amendment to authorize ██████████ change of location and it would be processed expeditiously by RI. ██████████ said ██████████ refused to submit an amendment unless it could be processed by Tuesday morning (December 14, 1992) so that ██████████ could resume licensed activities on that day (Exhibit 3).

██████████ said ██████████ considered issuing ██████████ a CAL but ██████████ did not because there was no reason to believe ██████████ would comply with the requirements of a CAL. Subsequently, based on 10 CFR Part 30.41, RI advised SYNCOR, and other pharmacies in the vicinity of ██████████ by letter dated December 11, 1992, that ██████████ was not authorized to receive shipments of NRC licensed material at the new location. ██████████ said that prior to this action, ██████████ advised ██████████ by telephone on December 11, 1992, that ██████████ would not be receiving any more shipments of licensed material at the new location because ██████████ NRC license did not authorize ██████████ to do so (Exhibits 3 & 5).

According to ██████████ NMSS was aware that additional clinical options were available to ██████████ patients if ██████████ clinic was not open. Although ██████████ could not recall specific details, ██████████ did explain how this type of issue is routinely handled. ██████████ said RI staff reviews a data base of NRC license holders for a specific area to ensure that additional licensees are available to provide a similar modality of treatment to patients affected by any NRC actions. ██████████ said the welfare of patients is taken very seriously in cases where action is to be taken against an NRC licensee.

██████████ said ██████████ was not sure how the decision was made to contact the pharmacies or who made it, but since NRC Headquarters was on board, ██████████ felt comfortable with this course of action. ██████████ said ██████████ does not recall taking this type of action before, however, ██████████ had violated ██████████ license, lied, and refused to cooperate with NRC staff (Exhibit 6).

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[redacted] recalled that based on discussions between RI and the Office of Enforcement (OE), a DEMAND was issued to [redacted] to obtain information regarding [redacted] use of NRC licensed material at a location not authorized by [redacted] license. [redacted] also said a CAL was not issued because [redacted] would not agree to stop using licensed material when asked to do so by [redacted] there was no reason to believe [redacted] would comply with the requirements of a CAL (Exhibit 4).

[redacted] said a DEMAND was issued to [redacted] and that [redacted] license could have been suspended or revoked if the NRC was not satisfied with [redacted] response. According to [redacted] the effort and resources involved in obtaining an Order Suspending or Revoking [redacted] NRC license would have been inappropriate and unnecessary because there was no significant health and safety concern. [redacted] said the licensed material that [redacted] used (Tc-99m) had a 6 hour half-life and was less dangerous than most isotopes. In addition, [redacted] could not receive additional shipments of Tc-99m because SYNCOR had been contacted and informed that [redacted] was not authorized to receive licensed material at the new location (Exhibit 5).

James LIEBERMAN, Director, OE, said a DEMAND was issued to [redacted] to obtain information regarding [redacted] open and notorious violation of NRC regulations. LIEBERMAN said a CAL was not issued because [redacted] had refused to voluntarily cease licensed activities at the new location when asked to do so by a member of RI staff. LIEBERMAN recalled that RI advised [redacted] daily suppliers of NRC licensed material that [redacted] was not authorized to receive shipments of NRC licensed material at the new address. According to [redacted] OE, suppliers were informed that NRC regulations prohibit the transfer of NRC licensed material to a location not listed on an NRC license. This action, in essence, suspended [redacted] license as it prevented [redacted] from obtaining any further licensed material at the new location. Consequently, LIEBERMAN said an Order to Suspend or Revoke [redacted] license would have been unnecessary (Exhibit 8).

[redacted] said an Order to Suspend or Revoke [redacted] NRC license was not issued because the material [redacted] used had a 6 hour half-life and was of no immediate public health and safety concern (Exhibit 3).

After reviewing the results of a December 1992 inspection of CAMEO that identified several violations, [redacted] believed [redacted] needed a RSO who was more familiar with NRC regulations. [redacted] was not aware of any discussions or actions that would have discouraged applicants from pursuing NRC approval as RSO on [redacted] license. [redacted] recalled that some applicants referred to the NRC by [redacted] may have withdrawn their names from consideration because of personal reasons.

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[redacted] said [redacted]'s current RSO, [redacted] was included as a license condition on [redacted]'s license and is required to conduct quarterly audits of CAMEO (Exhibit 5).

[redacted] said that two individuals who were referred to the NRC by [redacted] to be included on [redacted] license as RSO withdrew their names from consideration before the NRC could determine if they were qualified. One of these individuals, [redacted] contacted [redacted] after speaking to [redacted] and said [redacted] could not work for [redacted]. The second individual, [redacted] who is currently listed as RSO on a separate NRC license and who would have been qualified, also contacted RI and withdrew [redacted] name from consideration (Exhibit 7).

[redacted] and [redacted] recalled that [redacted] wanted to be designated as RSO on [redacted] NRC license but that [redacted] could not be approved because [redacted] failed to provide the required documentation demonstrating that [redacted] met NRC qualifications (Exhibits 2, 3, & 6).

[redacted] stated that during a December 29, 1992, inspection of CAMEO, [redacted] frequently commented about regulatory discretion and that RI should "turn their backs" to violations. According to [redacted] believes that NRC regulations should not apply to [redacted] because CAMEO is not a threat to the public health and safety (Exhibit 7).

[redacted] recalled that [redacted] repeatedly asked the NRC to exhibit flexibility in the enforcement of its regulations and to bend the rules for [redacted] (Exhibit 3).

[redacted] said that during an Enforcement Conference to discuss [redacted]'s violations, [redacted] said [redacted] using licensed material at the new location without authorization was a result of "sheer stupidity." According to [redacted] did not understand the significance of NRC regulations (Exhibit 5).

A CAMEO chronology maintained by RI and provided to OIG indicates that during the October 21, 1992, meeting at RI, [redacted] and [redacted] instructed [redacted] to change the address on [redacted] NRC license before [redacted] moved the location of [redacted] business (Exhibit 9).

A November 13, 1992, letter from RI to [redacted] summarizes the content of a telephone conversation that took place the previous day between [redacted] and [redacted]. This letter included the following information:

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You were informed that in order to commence use of NRC licensed radioactive materials at your new facility that you must apply for and receive a license amendment or license renewal which identifies the address where radioactive materials are used or possessed. This requirement is stated in the regulations (10 CFR 35.13(e)).

You may not begin to use NRC licensed radioactive materials at your new facility until such time as you receive an amendment to your license for change of use location or receive your completed license renewal.

This letter also advised [REDACTED] that if [REDACTED] decided to incorporate the change of location in [REDACTED] license renewal, it will take more time to complete than the expedited license amendment. The reason for this difference is due to [REDACTED]'s request to be exempt from NRC regulations with respect to surveys (Exhibit 10).

A Telephone Conversation Record dated November 19, 1992, indicated that [REDACTED] advised [REDACTED] "that [REDACTED] may not use NRC regulated materials at [REDACTED] new facility until such time as [REDACTED] has a license which includes [REDACTED] new address" (Exhibit 11).

A Telephone Conversation Record dated November 25, 1992, indicated that [REDACTED] left a message for [REDACTED] that included a reminder that [REDACTED] may not use NRC regulated materials at [REDACTED] new facility until such time as [REDACTED] has received [REDACTED] license renewal which correctly names [REDACTED] new place of use" (Exhibit 12).

In a December 14, 1992, note to the file [REDACTED] documented the content of a December 11, 1992, telephone conversation with [REDACTED]. During this conversation, [REDACTED] admitted that [REDACTED] had been using licensed materials at [REDACTED] new location. [REDACTED] stated to [REDACTED] that [REDACTED] runs a safe operation and when I [REDACTED] asked [REDACTED] directly if [REDACTED] would agree to stop using these materials since [REDACTED] was not authorized to use them, [REDACTED] said no."

[REDACTED] also indicated in [REDACTED] note that upon discussion with OE, it was decided that RI would "notify all suppliers to prevent [REDACTED] from obtaining materials from known suppliers. We [RI] drafted a letter based on OE's suggestion and faxed it to local pharmacies and major suppliers" (Exhibit 13).

In a letter to the NRC dated December 18, 1992, [REDACTED] provided [REDACTED] response to the December 17, 1992, Demand for Information. [REDACTED] said [REDACTED] continued to do business at 155 Maple Street because of "sheer stupidity." [REDACTED] said [REDACTED] "honestly and truly believed that Region I officials knew that I relocated to 155 Maple Street, Springfield, Massachusetts and had flexibility in administering the regulations." [REDACTED] added that, "My sheer stupidity was in not recognizing the gravity of the

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consequences of my efforts to save \$1,000. That is really and truly the entire basis for this deplorable mess I am now in (Exhibit 14)."

[redacted] sent the NRC a letter and enclosed a check of \$1,000 for an amendment request indicating a new location of 155 Maple street. The NRC received this letter on December 14, 1992 (Exhibit 15).

[redacted] Office of the Controller, advised OIG that, according to 10 CFR Part 170.31, Category 7C, the fee for [redacted]'s license amendment in December 1992 was \$460 and not \$1,000.

OIG contacted [redacted] MIT, to determine the circumstances surrounding [redacted]'s request that [redacted] serve as RSO on [redacted] NRC license. [redacted] said [redacted] did not pursue NRC approval as RSO because of the time and effort involved in verifying [redacted] credentials to the NRC. [redacted] said [redacted] may have lacked sufficient experience in the field of nuclear medicine to satisfy NRC requirements as an RSO on [redacted]'s license. [redacted] did not believe the NRC discouraged [redacted] from pursuing approval as RSO. [redacted] said [redacted] explained the reasons for [redacted] withdrawal to [redacted] (Exhibit 16).

[redacted] advised OIG that [redacted] decided to withdraw [redacted] name from consideration as RSO on [redacted]'s license after several friends advised [redacted] not to get involved with [redacted]. [redacted] said [redacted] felt as if [redacted] was less than forthright in [redacted] dealings with [redacted]. [redacted] said [redacted] advised [redacted] lawyer of [redacted] decision in this matter. [redacted] said [redacted] was not harassed by the NRC, and [redacted] was nothing but professional in [redacted] dealings with [redacted] (Exhibit 17).

10 CFR Part 35.13(e) states that a licensee shall apply for and must receive [emphasis added] a license amendment before it adds to or changes the areas of use or address or addresses of use identified in the application or in the license.

10 CFR Part 30.41(c) states that before transferring byproduct material to a specific licensee of the Commission, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred.

A fax from SYNCOR to [redacted] dated December 11, 1992, indicates that [redacted] was receiving shipments of Tc-99m from November 3, 1992, the date [redacted] re-opened at 155 Maple Street, until December 10, 1992 (Exhibit 18).

[redacted] SYNCOR, advised OIG that CAMEO was billed by SYNCOR for four doses of Tc-99m shipped to CAMEO on December 11, 1992. [redacted] added that this shipment was the last one made to CAMEO during the month of December 1992 (Exhibit 19).

FINDINGS

This OIG investigation determined that the actions taken by NRC staff with respect to [REDACTED] and [REDACTED] NRC license were in accordance with the provisions of 10 CFR. This investigation did not substantiate [REDACTED]'s allegations that NRC staff acted inappropriately with respect to the handling of [REDACTED]'s NRC license or that NRC staff exhibited a personal animus against [REDACTED].

OIG determined that, in accordance with 10 CFR Part 35.13(e), [REDACTED] was instructed by NRC Region I staff on several occasions not to use NRC licensed material at CAMEO's new address without first obtaining NRC authorization. To avoid paying the \$460 fee associated with obtaining a license amendment, [REDACTED] chose to incorporate CAMEO's change of address with [REDACTED] license renewal application which was being processed by the NRC. However, prior to receiving NRC authorization and despite notifications from NRC Region I staff that CAMEO's existing NRC license did not authorize the use of NRC licensed material at the new address, [REDACTED] used NRC licensed material at CAMEO's new address.

OIG also learned that NRC staff became aware that SYNCOR, CAMEO's supplier of NRC licensed material, was sending NRC licensed material to CAMEO's new address. This action violated 10 CFR Part 30.41(c). SYNCOR was notified by Region I that CAMEO's existing NRC license did not authorize CAMEO to receive shipments of NRC licensed material at the new address. SYNCOR promptly discontinued shipments to CAMEO. Prior to taking this action with respect to SYNCOR, Region I advised [REDACTED] that CAMEO would not be receiving shipments of licensed material. In a later Region I inspection, SYNCOR was cited for this violation.

OFFICIAL USE ONLY

Exhibits:

1. Interview of [REDACTED] dated 11/3/93
2. Interview of [REDACTED] dated 11/16/93
3. Interview of [REDACTED] dated 11/15/93
4. Interview of [REDACTED] dated 11/16/93
5. Interview of [REDACTED] dated 11/16/93
6. Interview of [REDACTED] dated 11/15/93 and Memo to File, dated 1/24/94
7. Interview of [REDACTED] dated 11/17/93
8. Interview of [REDACTED] dated 12/9/93
9. RI Chronology of CAMEO
10. Letter to [REDACTED] from RI, dated 11/13/92
11. Telephone Conversation Record, dated 11/19/92
12. Telephone Conversation Record, dated 11/25/92
13. Note to File from [REDACTED] dated 12/14/92
14. Letter to NRC from [REDACTED] dated 12/18/92
15. Letter to NRC from [REDACTED] undated
16. Memo to File, dated 12/1/93
17. Memo to File, dated 12/8/93
18. Fax from SYNCOR to [REDACTED]
19. Fax from SYNCOR to [REDACTED] dated 1/31/94