



Global Nuclear Fuel

A Joint Venture of GE, Toshiba, & Hitachi

Global Nuclear Fuel - Americas, LLC
P.O. Box 780, Wilmington, NC 28402
910-675-5000

November 30, 2000

Mr. Douglas M. Collins
Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region II
61 Forsyth Street, S.W., Suite 23T85
Atlanta, Georgia 30303-8931

Subject: NRC Inspection Report No. 70-1113/00-07, and Apparent Violation Regarding the Failure to Control Licensed Material in the Form of a Plutonium Calibration-Check Source

Dear Mr. Collins:

This letter confirms the telephone conversation between Mr. C. Monetta of Global Nuclear Fuel - Americas, LLC (GNF-A) and Mr. Ed McAlpine on November 22, 2000. During this conversation, it was agreed to postpone a previously scheduled pre-decisional enforcement conference on the above subject. The reason for the postponement was to give GNF-A until November 30, 2000 to submit in writing information demonstrating that the apparent violation should be categorized as a Severity Level IV rather than a Severity Level III violation.

As a preliminary matter, GNF-A agrees it failed to comply with NRC regulations regarding control of licensed material. GNF-A self-identified this noncompliance, reported the loss to NRC, and took prompt and extensive corrective actions to prevent recurrence. The loss is an isolated lapse in an otherwise exemplary material control program. Review of our records reveal this is the only time in over 30 years that GNF-A has lost a calibration-check source incident to shipment off-site. A repeat violation is unlikely. The only remaining issue is whether the resulting violation ought to be categorized as a Severity Level IV rather than a Level III violation and treated as a non-cited violation under NRC Enforcement Policy.

Mr. Douglas M. Collins
November 30, 2000
Page 2 of 2

Enclosed is information that GNF-A believes demonstrates this subject violation is most appropriately categorized as a non-cited Severity Level IV violation. Should NRC disagree with this assessment, we reaffirm our request for a pre-decisional enforcement conference to further discuss the subject violation.

Sincerely,

Global Nuclear Fuel – Americas, LLC



D. K. Dowker
FMO Plant Manager

Attachments

ATTACHMENT

I. Background leading to the identification and reporting of the event

As part of a regular self-audit on August 30, 2000, Global Nuclear Fuel-Americas LLC (GNF-A) identified that two sets of plutonium calibration-check sources were not in their expected storage locations. GNF-A first determined that the calibration-check sources had been sent off-site to be certified at Thermo NUtech's Albuquerque, NM facility. GNF-A next determined the calibration-check sources apparently were shipped from Thermo NUtech back to GNF-A on August 2, 2000. GNF-A then conducted an extensive search of the plant site and made the determination, on August 31, 2000, that the calibration-check sources were missing. As a result, GNF-A promptly notified NRC, issued an Unusual Incident Report, and initiated a Higher Level Critique.

The situation was promptly identified through a structured program that was designed to verify the control of sources. As a result of this identification management actions to investigate, report, determine root cause and take corrective and preventive action were quickly and appropriately set into motion.

II. Description of the items involved

The items involved were two sets of plutonium calibration-check sources that are routinely used at the site to calibrate radiation-measuring instruments. Each set is contained in a substantial wooden case as shown in Exhibit I. These wooden cases bear comprehensive identification including the identification of the type and quantity of radioactive material included inside. The wooden cases measure approximately 15" x 12" x 2".

Within each wooden case, there are four sources mounted in special holders as shown in Exhibit II. Each of the four sources is clearly marked to indicate the presence of radiation. The details of the special mount, which is approximately 9" x 2.5", can be seen in more detail on the left side of Exhibit III.

The planchet mounts for the standards are shown on the right side of Exhibit III. The planchet mounting ring (right top) is a metal ring of just slightly over 2" in diameter with an ~ 1.25" diameter hole in the center. During manufacture, the plutonium-239 is electroplated on the nickel metal disk and then fired in an inert atmosphere to thermally bond the electroplated plutonium to the nickel disk. This process results in the plutonium being tightly bonded to the nickel disk and produces a very stable source. The nickel source disk is then placed in the mounting ring and fixed in place with a retainer ring (right center). The source disk and mounting ring are then fixed to the special holders by three screws passing through the holder and being anchored in the three threaded holes visible in the mounting ring (right center).

The sources and their associated activity for each of the two sets of calibration-check standards is as follows:

Source	Activity, μCi
Set A, position 1	0.000276
Set A, position 2	0.00348
Set A, position 3	0.0377
Set A, position 4	0.334
Set B, position 1	0.00124
Set B, position 2	0.0108
Set B, position 3	0.122
Set B, position 4	1.121

This configuration is highly stable, as would be expected for standards that need to be highly reliable and constant in value. These particular two sets have been in routine service for approximately sixteen years. Over this period the quantity of radiation associated with each planchet has remained the same as the original value within the degree of measurement uncertainty.

The standards were shipped from the calibrating vendor in a single cardboard package 18" x 12" x 6". They were properly marked with all customary and required information to fully identify the shipper and the receiver. They were shipped as radioactive material, excepted package – limited quantity of material UN2910 and this was appropriate for the quantity and form of the material. The package was marked with the required labeling stating "This package conforms to the conditions and limitations specified in CFR 143.421 . . .".

It is clear that the items were properly marked internally, as radioactive material with all the customary labeling which was easily recognizable and capable of giving warning to any individual coming in contact with the items. Further the exterior package was also classified and marked properly both in terms of routine and customary markings for packages as well as those markings appropriate and required for the limited quantity of radioactive material. It is also indicative of the fact that any hazard associated with the materials was very low and that the attendant low hazard was properly mitigated through customary and required labeling.

III. Actions taken to locate

After reporting the missing sources and the report to the NRC, GNF-A continued actions in an attempt to locate the material.

Onsite, two additional site-wide searches were conducted. One was a general site-wide search and the other was a highly organized search. Both searches were supported by site-wide employee communications. Rewards were offered to any employee who located the missing package/items.

In addition to the site-wide searches, GNF performed a number of special focused searches in areas that were felt to be prime candidates for potentially locating the package.

Our onsite-receiving/onsite-delivery people reconstructed the most likely delivery routes associated with packages received on the date in question and these routes were retraced and searched.

The routine inventory of sources that originally identified the problem was completed.

All shipments and receipts of sources were stopped pending the completion of the investigation to a point where root causes were identified and revised controls could be adopted to strengthen the receiving routine.

GNF contacted and made several visits to the local UPS operations office. GNF spent considerable time learning about UPS procedures, systems and processes. UPS was very supportive in performing searches, systems queries and analysis. GNF also interviewed their delivery driver.

With help from UPS, GNF reconstructed the UPS delivery path for that day and we contacted all locations to verify that they did not get our package.

GNF contacted Thermo NUtech and confirmed that they had made three shipments including ours on the date in question. We verified the details of the packing and labeling for our shipment and contacted the receivers of the other two shipments to verify that our package had not been sent to them by mistake.

It is clear that GNF-A took comprehensive and exhaustive actions both on-site and off-site to locate the sources. Despite this effort, the sources have not been located. This indicates that the sources were most likely disposed of by accident, and are not in a location easily accessible by employees or the public.

IV. Root cause evaluation and corrective action

As a part of the investigation, a thorough root causes analysis was performed using TapRoot© and supporting methodology. Based on the lack of objective evidence, the root cause analysis findings had to assume that the package might or

might not have been delivered to the site. The most probable root causes based on this assumption are as follows:

- Receiving instructions did not require verification of the actual package tracking number against the carrier tracking number to confirm actual receipt from the carrier (an item count rather than a comparison of package tracking numbers was used as the basis for signing for receipt of the package)
- The established receiving process may not have been followed after physical receipt of this package from the carrier (package not received at Radiation Protection within 3 hours)

Based on these root causes, the following corrective actions have been implemented:

- Receiving procedures now require verification of the number of packages and individual carrier tracking numbers prior to accepting packages at GNF-A
- Personnel have been trained in the new procedure including the proper receiving process and the special handling required for packages containing radioactive material
- The instructions to vendors shipping sources and other small packages of radioactive material to GNF-A have been modified to require not only the customary labeling on the package but also to include "Attn: Radiation Protection Office"
- Procedures have been updated to require instructions be given to Shippers to notify the GNF-A internal contact with planned shipping information including shipping date and carrier information.

GNF has taken prompt corrective action that addresses the root causes.

V. This is an event of low safety significance and should be categorized as a SVL IV rather than a SVL III

The Enforcement Policy (NUREG-1600) sets forth, as guidance, four factors for assessing the significance of any violation: (1) the actual safety significance, (2) the potential safety significance, (3) the impact on the regulatory process, and (4) the willfulness of the violation.

In the area of health physics, the Enforcement Policy provides, as guidance, several examples of Level III and IV violations involving the failure to secure material. Those violations listed under Level III include events that involve the failure to control "licensed material in any aggregate quantity greater than 1000 times the quantity specified in Appendix C to Part 20." See NUREG-1600 on page 50, ¶ 11.

However, a better description similar to GNF-A's situation is provided in those examples illustrating Severity Level IV violations, given on page 51, ¶¶ 2-3, of the Enforcement Policy:

2. *A release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public as referenced in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under §20.1301(c));*
3. *A radiation dose rate in an unrestricted or controlled area in excess of 0.002 rem in any 1 hour (2 millirem/hour) or 50 millirems in a year*

Several facts demonstrate under the four factors the significance of this event is less than even the examples of a Severity Level IV violation.

The safety significance of the material lost is far less than the examples of Level III or IV would suggest. These examples use Part 20, Appendix C, values as a reference; however, in the case of Pu-239 Appendix C assigns risk based on the assumption that the material poses an internal exposure risk. Although the amount of material missing in this event, 1.7 μCi of Pu-239, is greater than one thousand times the Appendix C value for Pu-239, the Appendix C value is based on the assumption that the organ of concern is the bone surface (10 CFR 20, Appendix B). To realize exposure to the bone surface, the material would have to be either inhaled or ingested. The Pu-239, however, is electroplated onto nickel and contained on planchets. Based on the description in section II, a planchet can neither be inhaled nor ingested. Further, the Pu-239 is insoluble. Finally, the form of the planchet, *i.e.*, its size and the rim, discourages any type of repeated rubbing or polishing that could dislodge the Pu-239. The planchets in question have been in service for over 16 years and are handled at a minimum on a weekly basis. The calibration check of the sources performed immediately prior to their shipment from the vendor identified no measurable loss in radioactivity. In short, the Pu-239 will stay on the planchet, and will not become airborne or dissolved. For these reasons, evaluations of the safety significance based solely on comparisons to the limits of 10 CFR 20, Appendix C fail to give an accurate assessment of the safety significance.

The hypothetical exposure to an individual based on the radiation in the sources has been determined to be approximately 15 mrem committed effective dose equivalent (CEDE). This considers both inhalation and ingestion as discussed below. There is no external radiation hazard associated with these sources.

The inhalation pathway has been evaluated using the guidance provided in NUREG-1400 "METHODS FOR CONDUCTING AIR SAMPLING IN THE WORKPLACE". This guide provides a method acceptable to the Nuclear Regulatory Commission for estimating the potential for intake by inhalation for a

wide range of facilities, equipment and processes (Chapter 1, pages 1.1 through 1.3). The method described in NUREG-1400 begins by estimating the amount of material available for intake as being one millionth of the total amount of radioactivity processed by an individual in one year. Specified factors that consider the physical form of the material, the confinement of the material and dispersibility that may result from actions such as grinding or cutting modify this value. The amount of material available for intake in this case is one millionth of 1.7 μCi . The modifying factors are 0.00001 (solid material release fraction) and 10 (dispersibility factor for hypothetical non-accidental abrading). The estimated potential for intake using this method is $1.7\text{E}-10$ μCi , which is less than one millionth of the occupational intake limit (e.g. 10CFR20 Appendix B annual limit on intake for plutonium-239 is 0.006 μCi), and equates to a radiation exposure of significantly less than 1 mrem CEDE.

The ingestion pathway has been assessed by assuming 10% of the total activity is removed by abrading, contaminating the individual and the general area. It is further assumed that 10% of this contamination is ingested, which results in an intake of 0.017 μCi . The committed dose equivalent calculated from these assumptions using ICRP 68 dose coefficients for the material is approximately 15 mrem CEDE.

The cumulative quantity of material (1.7 μCi Pu-239) is directly comparable to the 1 – 2 μCi Am-241 used in smoke detectors. Am-241 has the same Appendix C value as Pu-239. These items are consumer products and exempt from regulatory controls after manufacture. They bear consumer labeling advising of the radioactive material content. The risk to the public from smoke detectors is very low.

Notwithstanding the low safety risk significance of the licensed material associated with the calibration-check sources, the devices are clearly labeled and it is extremely unlikely that an individual could come into possession of it without realizing the nature of the material. Labeling further mitigates the very low risk.

The loss did not occur because of a programmatic failure but rather was an isolated loss of control occurring for the first time in a program which has operated effectively for over thirty years.

The actions taken by GNF-A in this event are the actions that the NRC expects of its licensees. The problem was self-identified via an audit as a result of a questioning attitude. The licensee timely made all notifications required by law. The licensee kept the NRC informed at all stages of the investigation, and provided complete and accurate information. There is no evidence of any willful violation. For these reasons, GNF-A believes that there are minimal, if any, actual and potential safety risks resulting from this event, no adverse impact on the regulatory process, and no evidence of willful violation.

Reaching a conclusion that the safety significance of the material lost is equivalent to a condition warranting a Severity Level III enforcement action based solely on it slightly exceeding 1000 times the Appendix C value for Pu-239 is incorrect in this case. An evaluation of the hypothetical exposure magnitude from these sources indicates a conservative CEDE of approximately 15 mrem which is well below the exposure thresholds for consideration as a Severity Level III or IV and represent a very low risk exposure. This dose assessment when compared to comparable quantities of Am-241, which are approved for consumer products, yield similar conclusions with regard to the exposure risk of the Pu-239 in these sources. The low risk significance posed by these sources coupled with the fact that the license's response was consistent with what was expected, the licensee's performance has been very good for over 5 years and that there was clearly no willfulness exhibited by the licensee, all clearly supports the fact that a SVL III enforcement action is not warranted.

VI. This event is a SVL IV and is justified as a NCV

GNF-A recognizes this event as an apparent violation of 10 CFR § 20.1802 due to the failure to control and maintain constant surveillance of licensed material. However, under the facts of this event, GNF-A asks that this apparent violation be treated as a Severity Level IV non-cited violation, since the non-cited and Level IV criteria best fit these circumstances.

As discussed above, the material met the packaging requirements. The interior packages containing the material are clearly marked as Radioactive Material therefore unlikely to be inadvertently handled.

This event is the first occurrence of this type in over thirty years of licensed operations. Because the program and procedures in place during that time had successfully prevented loss of material in connection with receipt of packages from a common carrier, GNF-A feels that this event is not evidence of any sort of programmatic failure, but rather is an isolated occurrence.

Given the facts of this event, including the physical properties of the licensed material involved, the guidance contained in the Enforcement Policy supports a finding of Severity Level IV, rather than Severity Level III. Because GNF-A's apparent violation was self-identified, aggressively corrected, isolated, and not willful, this event should also be considered a non-cited violation. *See* NUREG-1600, Section VI, A.

Similarly situated licensees with similar events and similar responses have received non-cited violations from NRC. For example, in EA-1-2000-055, Allegheny General Hospital lost, and never recovered, a 14 mCi Am-241 source (which is fourteen million times the amount listed in Appendix C). The hospital

also engaged in an unauthorized transfer of 100 μ Ci of tritiated thymidine. However, the NRC considered these violations to be non-cited violations "because they were self-identified and immediate comprehensive corrective actions were taken by" the licensee. As documented in Event Number 36904, the Honeywell Corporation lost 10 mCi of Po-210 (one hundred thousand times the amount listed in Appendix C), but there is no record of a Severity Level III enforcement action against the licensee. Likewise, in Event Number 36563, the licensee Advanced Input Devices also lost 10 mCi of Po-210 and received no enforcement action.

As discussed in the prior sections, the event discussed here is clearly no more than a SVL IV violation which was promptly self-identified and self-corrected by the licensee and in all other respects meets the tests provided for in the enforcement policy to be a Non-Cited Violation (NCV). This treatment under the policy also appears to be consistent with other similar situations in the past.

VII. Conclusions

In this case, although there has been a loss of control of material, there is no evidence that exposure has resulted from that loss. Further, even if there were an exposure from this event, our calculations reveal that risk associated with this event fall below the guidelines for finding a SVL IV. Finally, in this case, the event was self-identified by the licensee, prompt notification, root cause analysis and corrective action occurred, and there is little, if any, indication that a programmatic failure is present. In these types of cases, GNF respectfully submits that both the NRC's guidance and prior practice dictates that the result for this event should be a non-cited, Severity Level IV violation.

OATH AND AFFIRMATION Executed pursuant to 28 U.S.C. § 1746

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 30, 2000.



D. K. Dowker

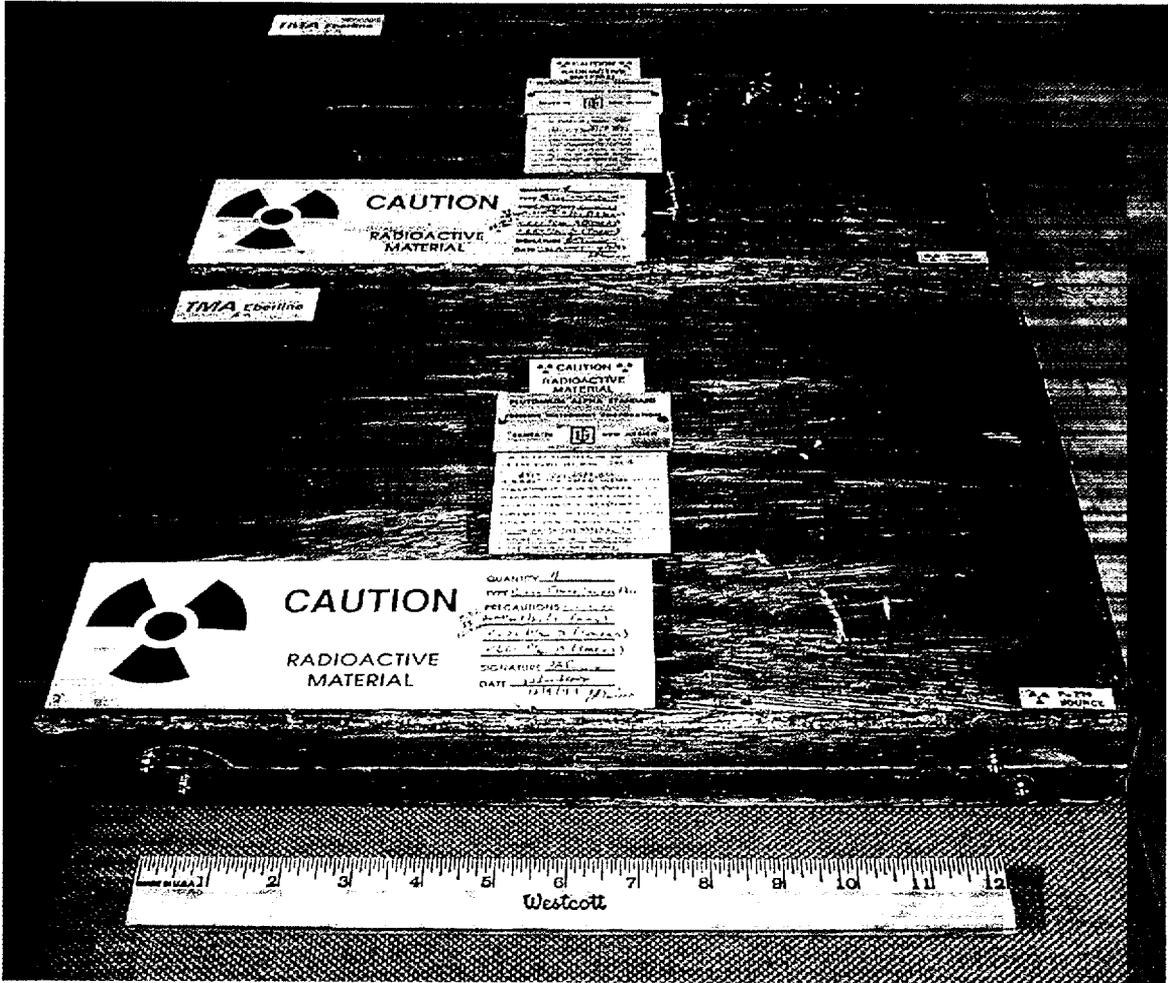


Exhibit I Calibration Set Cases



Exhibit II Calibration Source Holders

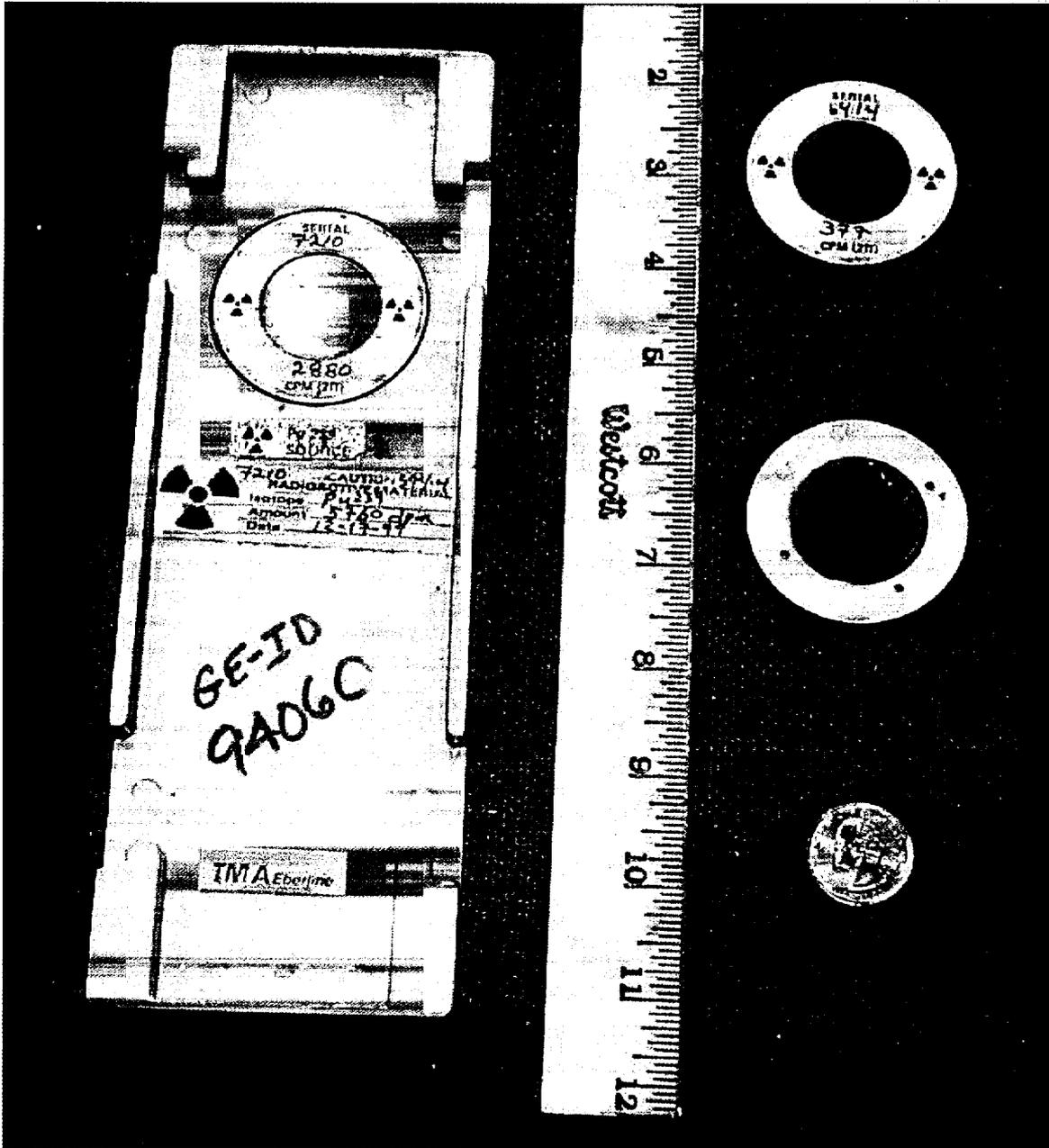


Exhibit III Planchet and Source Holder Details