**PREDECISIONAL ENFORCEMENT CONFERENCE SUMMARY**

Licensee: SABIA, Inc.

Facility: Idaho Falls, Idaho

License No.: 11-27727-01

Docket No.: 030-35997

EA-08-237

On November 10, 2008, representatives of SABIA, Inc. met with NRC representatives in the Region IV office located in Arlington, Texas, to discuss the apparent violations identified in NRC Inspection Report No. 030-35997/2008-001. The predecisional enforcement conference was held at the request of the NRC.

On November 8, 2008, the licensee submitted a letter to the NRC that provided their review of NRC Inspection Report No. 030-35997/2008-001 and listed their corrective actions. During the predecisional enforcement conference, the licensee discussed their position as outlined in their letter. Licensee representatives noted that they believed that the cause of the strontium-90 contamination event was a leaking strontium-90 source. Licensee representatives stated that they furthermore believe that either: (1) the gauge that was dismantled contained a source other than as described on the gauge label, (2) the strontium-90 source was not manufactured as described in its Sealed Source and Device Registration information, or (3) the strontium-90 source had turned from a glass disc into a fine powder during its lifetime.

Licensee representatives agreed with the first apparent violation regarding 10 CFR 20.1101(a), which requires, in part, that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

Licensee representatives disagreed with the second apparent violation regarding License Condition 14.E. of NRC Byproduct Materials License 11-27727-01, Amendment No. 10, dated November 7, 2007, which requires, in part, that that when sources are removed from storage for use and have not been tested within the required leak test interval, they shall be tested before use. The licensee's position was that, although it was not documented, the gauge that contained the strontium-90 source was tested for removable radioactive contamination prior to beginning any dismantlement activities or use of the source.

In addition, licensee representatives described their corrective actions as outlined in their letter dated November 8, 2008. Licensee representatives were asked to provide to NRC, within two weeks of the date of the conference, additional information regarding their corrective actions. Specifically, NRC representatives requested copies of the licensee's company-wide safety review, copies of the procedures that were revised and/or developed by the licensee as a result of the event and/or safety review, and a copy of the training materials that were developed by the licensee.

Interested members of the public were invited to observe the conference in person or through a teleconference bridge. Some members of the public asked questions of the NRC or made statements to the NRC before the conference was adjourned. Comments from the public

included a discussion of the need for licensees to directly notify local emergency responders when incidents, such as when a spill of a radioactive (hazardous) material occurs. NRC representatives noted that this subject was currently under review by NRC.

The attendance list and the NRC's presentation are attached to this summary. The licensee's November 8, 2008, letter to NRC has been made publicly available and can be located at ADAMS ML083170331.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this summary and its enclosures will be made available to the Public.

Attachments:
1. Attendance List
2. SABIA letter dated November 8, 2008 (ADAMS ML083170331)
3. NRC Presentation

| PREDECISIONAL ENFORCEMENT CONFERENCE ATTENDANCE | |
|---|---|
| LICENSEE/FACILITY | SABIA, Inc. |
| DATE/TIME | Monday, November 10, 2008<br>8:00 AM – 12:30 PM |
| CONFERENCE LOCATION | US Nuclear Regulatory Commission Region IV<br>Training Conference Room<br>612 E. Lamar Blvd. Ste. 400<br>Arlington, Texas 76011 |
| EA NUMBER | 08-237 |

| LICENSEE REPRESENTATIVES | | |
|---|---|---|
| **NAME (PLEASE PRINT)** | **ORGANIZATION** | **TITLE** |
| John Hagley | SABIA, INC | Coal Division Manager |
| Clinton Lingren | SABIA Inc. | President |
| JAMES MILLER | SABIA INC. | V.P. TECHNOLOGY |
| | | |
| | | |
| | | |
| PUBLIC OBSERVERS: | (in person) | |
| DAVID A. SILVERS | U.S. DOC | ATTORNEY |
| John Guenther | U.S. Doc | Attorney |
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ATTACHMENT 1

| PREDECISIONAL ENFORCEMENT CONFERENCE ATTENDANCE | |
|---|---|
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| EA NUMBER | 08-237 |

**NRC REPRESENTATIVES**

| NAME (PLEASE PRINT) | ORGANIZATION | TITLE |
|---|---|---|
| MARK HAIRE | NRC | SENIOR ENF. SPEC. |
| Karla Fuller | NRC | Regional Counsel |
| Art Howell | NRC | Director, DNMS |
| JACKIE WHITTEN | NRC | Chief, NMSB-B |
| Janine Katanic | NRC | Health Physicist, FSME |
| G. Michael Vasquez | NRC | Acting Chief, NMSB-A |
| Susanne Woods | NRC | Enforcement Specialist |
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November 8, 2008

Arthur T. Howell, III, Director
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region IV
612 East Lamar Blvd, Suite 400
Arlington, Texas 76011-4125

Subject: NRC Inspection Report 030-35997/08-001

Dear Mr. Howell,

We have reviewed the referenced NRC Inspection Report and have again addressed the corrective actions taken by SABIA Incorporated since the event that contaminated our facility with strontium-90 on February 29, 2008, and the days that followed. The facility cleanup has been completed and nuclear sources that had been stored at that facility have been removed and shipped or prepared for shipping to other sites for final disposal.

Our review of the referenced Inspection Report has also included review of related activities before and after the event and of accounts by each of the individuals who were present during the event that were written immediately thereafter. This evaluation has also included review of corrective actions that have been taken and additional root cause analyses.

Our review has uncovered some details that were missing from the report and some discrepancies between accounts and between the Inspection Report and accounts that were given. These are summarized in the enclosure and will be pertinent to discussions at the predecisional enforcement conference on November 10, 2008, in your offices in Arlington, Texas.

We appreciate the opportunity of meeting with you and look forward to a meeting that is productive and beneficial for all participants and for our industry.

Sincerely,

Clinton Lingren, President/CEO
SABIA Inc.

ML 083170331

Attachment 2

**Review of NRC Inspection Report 030-35997/08-001**

SABIA Inc. has carefully reviewed the subject Inspection Report and available information related to that report. The consequences and implications of the strontium-90 source leak must not be minimized in any way. The reviews that have been done have identified weaknesses in the planning and procedures in use when the leak occurred and corrective actions have been and are being implemented. Though the source disposal program that was being carried out at the time of the leak has been judged inadequate because of the leak, it had been judged adequate when the work began and had been submitted to the NRC prior to beginning the project. The Inspection Report is very detailed and thorough; however, SABIA Inc. takes exception to a number of the conclusions.

The cleanup of the facility was a long and expensive process. Because of the magnitude of the contamination inside the facility, state and federal agencies followed the paths of the employees that had been present when the leak occurred in search of the spread of contamination. No contamination was found. Industry experts who have helped with the evaluations and cleanup have expressed admiration that the employees handled such a major leak and were able to decontaminate themselves and close up the facility without any spread of contamination outside the facility.

Our review of the referenced Inspection Report has also included review of related activities before and after discovering radioactive contamination (the Event) and of accounts by each of the individuals who were present during the Event that were written immediately thereafter. This evaluation also included review of corrective actions that have been taken and additional root cause analyses. It uncovered some details that were missing from the report and some discrepancies among the Inspection Report and employee accounts that were given.

<u>Details that were missing from the Report</u>

1. Section 2.2.2, "Sequence of Events Leading to the Discovery of Radioactive Contamination" describes many pertinent details related to the Event. However, a description of the flow of the work involved is also pertinent to this report.

   The nuclear sources that were being prepared for final disposal were in industrial gauges that had been removed from locations where they were no longer in use throughout the United States, and the gauges were stored on shelves in wooden shipping crates in which they had been received. In some cases these crates contained gauges from more than one shipment.

   The crates were moved from the shelves to the floor of Bay 3 as they were being processed. When a crate was placed on the floor, the lid was removed and the gages were leak tested before being removed from the crate. The gauges were then staged near the location where the source would be removed from the gauge and placed in a lead housing for shipment for final disposal.

2. Section 2.2.5, "NRC, State, and Local Response to the Contamination Event" describes the NRC Inspector's interviewing SABIA employees and the initial visit to the SABIA facility. That description fails to mention the entry through the front door by the NRC Inspector with Employee #1 and Employee #2 into the office area of SABIA Bay 4. The NRC Inspector laid personal items on the desk and took photos of what could be seen in the back, high-bay area from the carpeted office area. The NRC Inspector also took several radiation readings with a meter. The employees noted that they could hear the air-conditioner blower in the back, though they had thought it had been turned off. The three were in their street clothes because the extent of the contamination was not yet known and they did not have protective clothing at that time.

Discrepancies in information and among employee accounts and the Inspection Report

1. The precise time with respect to gauge dismantlement that the wipe was taken that identified the radiation leak is in question.

   A summary of the event written by Employee #1 on March 1, 2008, states, *"I disassembled the gauge as I had done on all of the previous gauges. This gauge had a stainless steel source holder inside. I removed the source holder. It had a piece of some type of foil about 1.5" x 1.5" over the source window. I removed the foil and removed the top cover to the holder. There was a stainless steel screw covering a hold in the back of the holder. I removed this as well. I could visually see the SR-90 source in the holder. It was about the size of a Tylenol pill. In order to fit this source into the lead pig it was going to need to be removed. I turned it over and tapped it on the table. I wouldn't move. I then took a screwdriver and just barely tapped it twice. It still didn't move but I dented the source. I immediately had* [redacted] *swab the source. I proceeded to try to get it out so I could get it off the table and into a pig."*

   However, a summary of the event written by Employee #2 (who did the wipe tests) on March 5, 2008, states, *"I came back into bay 3 about the time he was removing the small source housing off the main housing of the gauge.* (Employee #1)*... was working on the gauge on the work bench to the left of the lead bricks. I had the swipes ready and bags labeled. When he pulled the small housing off, exposing the source, I immediately swiped the source, bagged it, and then swiped the housing where the source was sitting. I immediately took them to bay 4 to count."*

   In evaluating this discrepancy, Employee #2 pointed out that, as they worked together, they were directly in contact with each other because of the smallness of the device and the work area. Because of their closeness, had Employee #1 tapped the device on the cardboard or tapped it with the screw driver while Employee #2 was there, he (Employee #2) would have had a similar amount of contamination on his clothes as did Employee #1. But the amount of contamination on Employee #2 was much, much less, which appears to confirm the account by Employee #2.

2. The precise time with respect to gauge dismantlement that Employee #1 was notified that there was a possible radiation leak is in question.

The NRC Inspection Report, page 11, last paragraph of section 2.2.2, states, *"Employee #2 informed Employee #3 that he suspected that something was wrong with the instrument. In an attempt to resolve the suspected problem, they brought the instrument to the front of the office area of Bay 4 and changed the batteries. After the batteries were changed, the instrument was turned on with no swab inside of the unit, at which time the instrument display immediately indicated several thousand counts. It was at this point that Employee #2 recognized that there may be actual radioactive contamination and informed Employee #1 to 'Stop!' and discontinue his activities involving the strontium-90 source."*

The summary written by Employee #2 states, *"The first swipe (I don't remember, if it was source or housing) created large counts. I had made mistakes with the meter before, so I tried to reset it, but the counts stayed above 3000. I wasn't sure if it was a meter failure or the real thing. About 15 sec went by or so it seemed. I went right to bay 3 and told* (Employee #1)*... to stop what he was doing, that we had a problem and had to determine if my reading was correct."*

The summary written by Employee #1 states, *"About this time (Employee #2)... came running over and told us to stop what were doing as there was a problem with a meter. I just stopped working. I removed my gloves at this point with pliers not wanting to take any chances. I waited a min and then walked over into the other bay suspecting a technical problem with the meter. He changed the batteries in the meter and still had the same results. We then placed one of the Ludlum meters over the wipe at a distance of about ¼" and it went off."*

The four accounts of the four employees differ with respect to the exact time that Employee #2 notified Employee #1 to stop work on the source. This is quite normal in as much as each was focused on his/her own function. It is most likely that the employee who gave that notification would know exactly when it was given. Therefore, we conclude that the account of Employee #2 has the highest probability of being reliable in this instance. Likewise, a time-motion evaluation of the actions of Employee #1 and of Employee #2 match when using the account of Employee #2 for establishing the time of the wipe and of the notification to stop. What is certain is that Employee #2 told Employee #1 to stop work as soon as it appeared that there could be a problem and prior to evaluating the operability of the meter.

3. The descriptions of the strontium-90 source and gauge were uncertain.

The gauge had a metal label attached indicating the Manufacturer, Model Number, Isotope, Activity, and Date. The identification was Manufacturer: **Dupont-Merck**, Model Number: **NER-592**, Isotope: **Sr-90**, Activity: **100 mCi**.

There was no device label on the gauge housing, and nothing relating anything to the original customer or to the original device. The company files indicate that this was originally shipped from 3M, and the original service purchase order from 3M identified the gauge as being an **LFE Model SULP-1C**.

There were no labels, nameplates, or device labels on the housing to indicate anything except the Dupont-Merck Model NER-592. Certainty that the identification as the LFE Model SULP-1C was correct is based on the knowledge that it was only gauge containing Sr-90 that SABIA had ever received.

The LFE Model SULP-1C gauge is registered as a custom device, specified to contain Sr-90 sources manufactured by LFE. Alternatively, the gauge is also authorized to contain Kr-85 sources manufactured by LFE or by Amersham. The device registration for the gauge does not mention sources manufactured by Du Pont Merck.

Device Registry No. NR-476-S-829-S for the Du Pont Merck Pharmaceutical Co. model NER-592 Beta source give the following description: **"The NER-592 source consists of strontium/yttrium-90 oxide/silicate fused in a glass disc and sealed by welding in a 316L stainless steel capsule. The capsule body is 0.27" (6.86 mm) long by 0.40" (10.2 mm) in diameter and has a wall thickness of 0.030" (0.762 mm). the radioactive material is stored behind a 0.003" (0.076 mm) stainless steel window which is electron beam welded in place. An aluminum spacer is placed behind the radioactive material followed by the source plug which is TIG welded in place. The source plug may be machined with a mounting fixture."**

Eckert & Ziegler (formerly Isotope Products Laboratory) now own the source registrations, which were purchased from Du Pont Merck. The engineer at Eckert & Ziegler stated that the source is supposed to be fused into an inert form, non-reactive, non-soluble, and non-dispersible. He, of course, could not verify that the Merck source had been made according to specifications.

We have not been able to find any industry notifications nor records of fused glass discs of strontium/yttrium-90 sources disintegrating to cause an extreme contamination risk as we encountered.

4. The NRC Inspection Report, page 25, second paragraph of section 5.2.3, states, "*Employee #1 also did not recognize that it would be inappropriate to shield this type of source with a high atomic number material such as lead.*" During the assessment of the Event, several statements were made with respect to the hazard of placing the Sr-90 source in a lead shield container. The magnitude of this hazard needs to be quantified.

The energy of a Sr-90/Y-90 source is 546 kev for the Sr-90 and 2.283 Mev for the Y-90. The maximum energy of a photon generated by absorption of the beta particle (Bremsstrahlung) is 2.283 Mev divided by 3, or about 760 kev. For beta particles of 2.283 Mev, and for interaction with lead, approximately 6.25% of the incident energy is lost as photons (high energy X-rays). In other words, for a Sr-90/Y-90 source of approximately 70 mCi, the effect inside of a lead shield would be approximately equivalent to the addition of a 5 mCi source of Cs-137. The lead shield was 2 inches thick. Therefore, the Bremsstrahlung radiation at the outside of the lead shield would be negligible since the shield design was adequate to contain 6 Curies of Cs-137.

Though a lead shield is not the normal choice for a Beta radiation source, from a Radiation safety standpoint, the use of the 2 inch thick lead shield was not a safety issue in the work performed on this Sr-90/Y-90 source.

Root Causes of the Event

The company was not prepared for the radioactive contamination event that occurred. As a result of the Event, we have reviewed our procedures and methods of working, have re-written procedures, added new procedures, and have added increased training capability to the company staff. Major contributing causes to the severity of the event are listed below.

1. The Event was the contamination of the SABIA Inc. manufacturing facility in Idaho Falls, Idaho, on February 29, 2008.

2. The cause of the Event was a leaking Sr-90 Beta emitting source that was being prepared for disposal.

3. The cause of the leak was deterioration of the source during the 20 years since its manufacture, which may have been precipitated by striking it with a screwdriver. The extent of the dispersion of contamination was significantly increased by striking the source in its holder on a cardboard-covered workbench and on the metal surface of a nearby electric table saw.

4. The rough handling of the source was a result of lack of understanding of the risk and of the structure of the source and lack of sufficient oversight.

5. The lack of understanding reflects a weakness in the planning, preparation, and training for the task at hand. The planning, preparation and training presumed that all sources could be handled as the cesium and americium with which the company had long experience.

6. The strontium-90 source that leaked was the only one of its kind with which the company employees had dealt, and, therefore, they had no prior experience with that source. The planning did not recognize the risk involved nor the special handling that might be required for this source.

7. When a customer requested the company to accept the strontium-90 source for disposal, the SS&D was reviewed, but it led the reviewer to the conclusion that the source material was in an inert, non-dispersible form in a welded stainless steel capsule. It therefore would not present a high risk of contamination. That erroneous conclusion affected the entire process of planning, preparing, and training for the source disposal effort.

8. The Sr-90 source was not as represented in the SS&D. There are three possibilities: 1) the gauge was mislabeled with the wrong source model information, 2) the source

was manufactured as a powder rather than the source material being fused into a glass disc, 3) the glass disc was turned into a fine powder by the energy of the Beta radiation during its 20-year life.

Corrective Action taken as a result of the Event

SABIA Inc. has taken several steps to ensure that there is never a repetition of this type event.

1. The company has ceased to offer source disposal services to our industry except in the capacity of helping the customer ship unwanted sources to an appropriate disposal site.

2. All sources previously stored at the company's Idaho Falls facility, except for a few americium-241 sources and the californium-252 sources that are used with our products, have been shipped or are ready to be shipped for disassembly in preparation for disposal. The americium sources will be shipped to OSRP.

3. The company has reviewed all of its procedures related to nuclear source handling, has revised some of those procedures and has prepared additional procedures where a need was identified. Several of the procedures had steps that were not specific enough to prevent multiple interpretations. These were expanded to ensure that every trained, licensed employee would perform the procedure in the same way.

4. The company has initiated a safety review throughout the company and has made changes where safety can be enhanced. The new or revised procedures have been reviewed and released.

5. The company has added employees with extensive background in training and technology and has initiated extensive training throughout the company. Each employee who is qualified to do work related to the new or revised procedures has been trained in their use and the bases upon which they are founded.

6. The company has instituted a requirement for project review by appropriate departments and project participants prior to initiating projects.

# NRC Enforcement Program

## Predecisional Enforcement Conference

## SABIA, Inc.

November 10, 2008

Arlington, Texas

Attachment 3

# THE NRC PROCESS

1. Inspection
2. NRC Review of Issues
3. EXIT MEETING (call) with Sabia, Inc.
4. Inspection Report w/APPARENT VIOLATIONS
5. PREDECISIONAL ENFORCEMENT CONFERENCE
6. NRC Review of ALL Information
7. FINAL AGENCY DECISION ON WHETHER ENFORCMENT ACTION IS WARRANTED

# FOR TODAY'S MEETING

1. **No Final Decision Yet**
2. **The Inspection Report provided NRC's perspective**
3. Today, We Want **Your Perspective**

- on ***whether violations occurred***, the circumstances
- identification and ***corrective actions***
- whether you agree with our ***characterizations*** in the inspection report
- any ***other information*** you want us to consider

# DECISIONS TO BE MADE

1. **WHETHER** violations occurred

2. **SIGNIFICANCE** of violations

3. **ENFORCEMENT** action (if any)

# POSSIBLE OUTCOMES

1. No Action
2. Notice of Violation (NOV)
3. NOV with Civil Penalty ($)
4. Order

# SIGNIFICANCE = "Severity Level"
# Civil Penalties are considered for Escalated Enforcement

**SEVERITY LEVEL – I**
(most significant regulatory concern)

**SEVERITY LEVEL – II**
(very significant regulatory concern)

**SEVERITY LEVEL – III**
(significant regulatory concern)

(Escalated Enforcement)

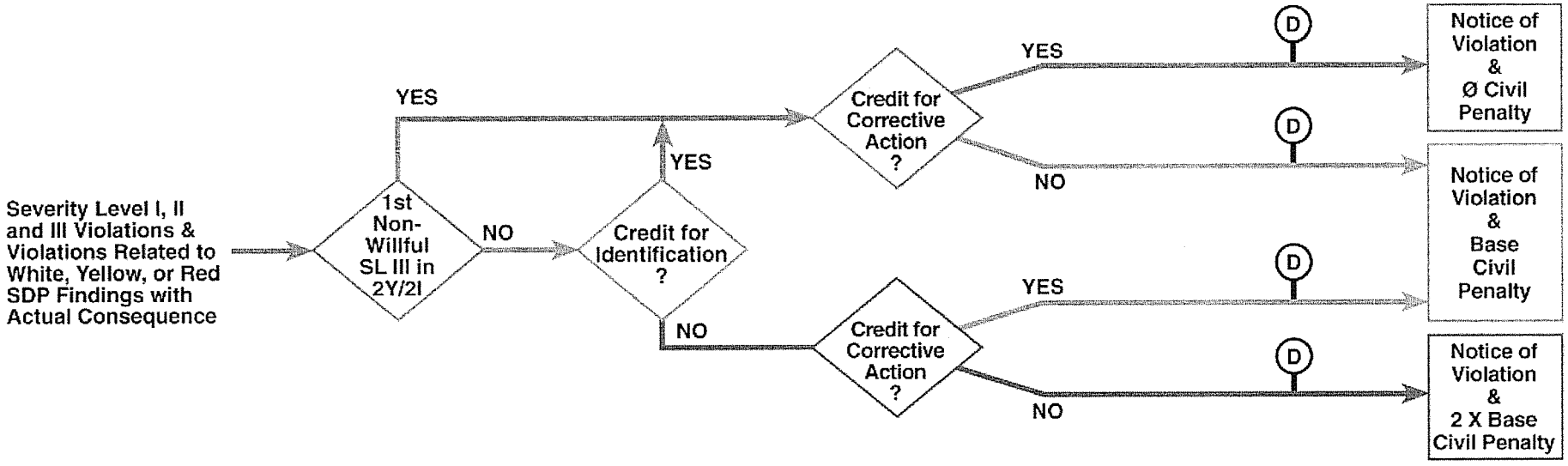
(Non-Escalated Enforcement)

**SEVERITY LEVEL – IV**
(less significant concern, but more than minor)

# DETERMINING SEVERITY LEVEL

- ✔ Actual safety consequences (e.g., overexposures)
- ✔ Potential safety consequences (e.g., potential for members of the public to be exposed)
- Impact the Regulatory Process (e.g., not reporting as required)
- Willfulness (e.g., deliberately failing to follow NRC regulations, deliberately not telling us the truth.

# CP: WHEN & HOW MUCH?



# BASE CIVIL PENALTY

## TABLE 1A--BASE CIVIL PENALTIES

| | | |
|---|---|---|
| a. | Power reactors and gaseous diffusion plants | $130,000 |
| b. | Fuel fabricators authorized to possess Category I or II quantities of SNM | $65,000 |
| c. | Fuel fabricators, industrial processors,[1] and independent spent fuel and monitored retrievable storage installations | $32,500 |
| d. | Test reactors, mills and uranium conversion facilities, contractors, waste disposal licensees, industrial radiographers, and other large material users | $13,000 |
| e. | Research reactors, academic, medical, or other small material users[2] | $6,500 |

| | |
|---|---|
| I | 100% |
| II | 80% |
| III | 50% |

# DISCRETION

- NRC may escalate or mitigate a civil penalty based on the circumstances of the case (more info is in the NRC Enforcement Policy).

- Examples where the NRC might exercise discretion include - willfulness, lost sources, overexposures,…

# PUBLIC INFO

1. If NRC takes enforcement action, it will be publicly available on web.

2. Normally, a **press release** will be issued if a civil penalty or an order is issued.

# APPEAL RIGHTS

1. Any NRC action may be challenged

2. Instructions for challenging an enforcement action will be described in the action

# Summary

- No final decision has been made
- Your corrective actions will be a focus
- Potential enforcement outcomes after today's conference:
  - (1) no action;
  - (2) NOV;
  - (3) NOV & civil penalty; or
  - (4) Order