



x6/11/88 RSI 33
Answer File

April 30, 1987

Docket No. 030-19025
License No. 04-19644-01
EA 87-28

Director, Office of Inspection and Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

Subject: Notice of Violation and Proposed Imposition of
Civil Penalty (NRC Inspection Report No.
030-19025/87001 (DRSS))

Pursuant to the provisions of 10 CFR 2.201, a written statement of explanation has been submitted to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, regarding the referenced Notice of Violation.

This statement is written in accordance with 10 CFR 2.205 to protest imposition of this civil penalty and to request total mitigation of the penalty. References to the above statements written in response to 10 CFR 2.201 will be made as appropriate.

Additional mitigating explanations will be provided to support our actions and position. Hopefully this additional input will be sufficient to permit the total mitigation of the proposed penalty.

RSI Philosophy & Regulatory History

During the past eight years, RSI has built and operated five large scale gamma facilities for the purpose of sterilizing medical disposable products. Two of our facilities are NRC licensed (Illinois and Ohio), and three are in Agreement States (California, Georgia, and Texas). In total, our history represents over 19 facility operating years. We have never had a personal exposure incident. We have greatly enhanced the radiation industry's image.

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Our rapport with the regulating agencies has been very cordial and cooperative. We feel that we have always been responsive to any and all regulatory requests. Deficiencies have always been attended to on a mutually acceptable basis. We are in full accord with the purpose of the NRC enforcement program which is to promote and protect the radiologic health and safety of the public.

All decisions made by RSI concerning facility operation are made with this purpose in mind. Perhaps there have been some decisions made by RSI which the NRC believes should have been reported or attended to in a more timely manner - which is part of the basis for this notice.

However, during our six years of NRC regulation, I feel that a trust and belief that RSI is a responsive and intelligent company had developed with NRC regulators. Inspections during this time period have resulted in citing up to four Level IV violations. Mutual agreement would be reached on the disposition, and the matter closed. We assumed that this was normal and an acceptable procedure. There was never a warning that repeated violations of this nature would result in severe civil penalties. We would have appreciated such a warning. We would appreciate the NRC considering this case to be our warning.

In recent discussions with the NRC, it was mentioned that they were now operating under a higher level of enforcement sensitivity. If this change had been transmitted to me, I assure you that this situation would never have arisen. A simple warning would have been sufficient to avoid this costly enforcement proceeding. Hopefully it can be stopped at this level.

Impact to Date

RSI, unlike the power industries, is in a very competitive industry. The publishing of the notice of proposed civil penalties has already impacted heavily on the relationships with many of our customers. Our competition is also using it to their advantage.

The imposition of any fine, regardless of amount, will

have a devastating effect on my business. Only a justified elimination of the fine can help undo the damage already committed. I hope that I have provided that justification.

Last March 28, RSI helped to fund and sponsor a test marketing of irradiated papayas at considerable expense. This test was undertaken in cooperation with GA Technologies of San Diego, and the Papaya Administrative Committee of Hawaii. Its purpose was to promote the irradiation of papayas to control the spread of fruit flies. The test was very successful in terms of customer acceptance.

There is considerable interest today in Hawaii to build a commercial scale papaya irradiator in the light of the recently imposed embargo on papayas to the U.S. from Hawaii. Currently accepted treatment processes have proven to be unacceptable. RSI is the only viable U.S. based equipment supplier, and we are working with a consortium of the papaya interests and legislators in Hawaii. The primary alternative is Canada.

Any fine levied against RSI will most surely be used by the Coalition Against Food Irradiation to stop this project. This organization is already using the press release on the proposed fine to their advantage. In fact they are claiming that RSI has been fined already. An imposed fine would be used against RSI and the industry in every other proposed food irradiation project. RSI would most probably be forced to get out of the food irradiation business. A fine imposed on RSI would cause considerable irrevocable damage. It would also provide ammunition to the enemies of the nuclear industry. A severe warning would definitely accomplish the NRC's goal.

RSI Actions to Date

Once having recognized the change in NRC enforcement policy sensitivity, RSI has expended considerable resources to respond to the NRC concerns, and to increase RSI's internal sensitivity regarding enforcement.

On January 19, 1987, I flew to Schaumburg to discuss the inspection with Tom Mates, the General Manager at Schaumburg. From there, I flew to Westerville to discuss

the matter with Barry Fairand the General Manager.

During the week of January 26, 1987, I had my QA Director fly to my Schaumburg, Westerville, Decatur and Fort Worth plants to review their systems and procedures. They were also appraised of a potential nationwide increased sensitivity to license enforcement.

My Vice President of Engineering flew to Schaumburg on February 2, 1987 to assure that the total safety system was in compliance with our license. Other engineering staff members were flown to Westerville and Decatur for similar reasons.

Additional safety precautions were taken during the week of February 12 when a physical gate barrier was installed in Schaumburg to prevent inadvertent maze access.

Licenses for Illinois and Ohio are being reviewed and reworked to eliminate all extraneous statements, and to change others to more workable conditions. In retrospect several of the cited license violations could have been eliminated by a more careful wording of the license.

The position of Director of Regulatory Affairs and Quality Assurance has been made a full time position with greatly increased responsibilities in the licensing and compliance areas.

It is now obvious that we have been operating under a misunderstanding of the NRC's enforcement policy. It appears that in the past, the emphasis was more on operating according to the intent of the license. It now seems like it is moving towards operating to the letter of the license.

Having recognized this we are taking all necessary steps to comply.

Schaumburg Management

Mr. T.W. Hurley was RSI's first General Manager. Due to a variety of reasons, he was terminated in August 1985. During his tenure, he caused some animosity with some of the employees.

This animosity resulted in two complaints to the Region. The two resulting inspections showed a single violation out of eight allegations. Even so the violation was due to RSI's commitment to personnel safety. Where the NRC requires only a single responsible individual be present, RSI stated that it has at least two operators present at all times. One person can operate the facility, but we use two in case of an injury. The citation was for a two hour period when an employee worked alone. To my knowledge this was the only single operator occurrence in 6 years of operation.

Enclosed is a copy of the NOV for the March 14, 1985 inspection. From my handwritten notes to Hurley, you can see that I had concerns over the time periods of inaction, and dissatisfaction over his performance. Even though I was listed for a copy of his response, I could not find it in my files.

We have not had any employee problems over the last year. This has been in large part due to the assignment of Tom Mates as the new General Manager last April. His relative inexperience may have been a mitigating factor. i.e. the call list.

Each of the alleged violations will be individually addressed. References are as noted in the 10 CFR 2.201 response letter. Each section should be read in conjunction with the corresponding information in this letter. Many of the arguments for mitigation are contained in the 10 CFR 2.201 response, and will not be repeated here.

As requested the five factors addressed in Section V.B of 10 CFR Part 2, Appendix C will be addressed as appropriate.

IA

We do not contest this alleged violation, and do not agree that it was a repeat violation. Refer to 10 CFR 2.201 response.

- (1) Schaumburg is equipped with an electrical test circuit which checks only the wiring from the device to the safety system. This test was routinely run up until October 1986. At this time

an inspection of the smoke and fire detectors showed they were badly corroded and inoperative. At Schaumburg the exhaust duct is exposed to the elements as are the detectors.

Replacement units were ordered. Since the detectors were inoperative, the test circuit checks were not run and so noted on the monthly check list. There was no attempt to hide anything.

- (2) Refer to 10 CFR 2.201 response.
- (3) We have always been under the impression that our past performance has been acceptable to the NRC. We have never had any indication to the contrary before this inspection.

Regarding the charge of a repeat violation, the first was for a total absence of any monthly test in Schaumburg. In this instance the monthly tests were run and it was documented that this specific test was not run. The reason being as listed in (1) above.

The 10 CFR 2.201 response explains that the alleged violation for Westerville was the result of a misunderstanding. Our monthly checklists showed that these tests were not being run, yet we were told we were in full compliance. The copies of the monthly inspection sheets used during the May 15, 1985 and August 5, 6, 1985 inspections were enclosed with the 10 CFR 2.201 response.

- (4) There was no prior knowledge of the failed units.
- (5) There were not multiple occurrences of this item.

IB

We do not contest this alleged violation, and do not agree that this is a repeat violation.

- (1) There has been a basic misunderstanding on our part regarding reporting and prompt corrective action. In the past we assumed that only significant safety related items need to be

reported, and that good engineering judgment should be exercised regarding corrective action. This has been explained in our 10 CFR 2.201 response.

This misunderstanding has been cleared up and we will act accordingly.

- (2) Refer to 10 CFR 2.201 response.
- (3) The cause of the prior beacon failure was a burned out bulb. The cause of this beacon failure was a disconnected wire. Accordingly the second failure could not have been prevented by the corrective action for the first. It should not be considered a repeat violation.
- (4) There has been no prior notice of similar event.
- (5) There were no multiple occurrences.

IC This alleged violation is denied.
 Refer to 10 CFR 2.201 discussion.

ID We do not contest this allegation.

- (1) Refer to IB (1).
- (2) Refer to 10 CFR 2.201 response.
- (3) There has been no prior concern in this area.
- (4) There has been no prior notice of a similar event.
- (5) There were no multiple occurrences.

IE This alleged violation is denied.
 Refer to 10 CFR 2.201 discussion.

IF This alleged violation is denied.
 Refer to 10 CFR 2.201 discussion.

IG This alleged violation is denied.
 Refer to 10 CFR 2.201 discussion.

IH We do not contest this alleged violation.
 Refer to 10 CFR 2.201 discussion.

Alleged Violations

Of the eight alleged violations, we feel that four are not justified and deny them. These pertain to:

1. Malfunctioning door
2. Definition of adequate cell check
3. Internal operating procedure (tags)
4. Unnecessary seismic detector

One of the alleged violations which was not contested, but which we feel that we were in compliance was:

5. Posted call list vs. wallet lists

Two of the alleged violations, which are not contested were directly related to our safety system improvement program. Both were either inadvertent or accidental.

6. Removal of timer on fill line (inadvertent)
7. Beacon and sign were disconnected (accidental)

The last non-contested alleged violation attributed to a misunderstanding of reporting requirements, and the absence of an inadequate test:

8. Smoke and fire tests

Repeat Violations

The two instances of alleged repeat violations are denied on the basis that proper corrective action was implemented for the first offense, and could not possibly have prevented the two current alleged violations.

Breakdown in Management Controls

I do not consider that there has been a significant breakdown in management oversight and control of our radiation safety program. However, I can understand the NRC's position and concern which was based upon the inspection report. I hope that my itemized review of each item may offer you a different perspective.

I feel that there has been a breakdown or deficiency in critical communication between RSI and the NRC. I believe that we are partners in the nuclear industry with common purposes and goals. We are in the same boat.

I can assure you that a simple warning to me will always prevent an escalated enforcement procedure, thereby saving both organizations considerable grief. I fully understand that it is my responsibility to comply to all of the rules and regulations pertinent to licensing. However, since these are so voluminous, I would appreciate any help you can offer to make both of our lives easier.

Reasons for total mitigation of the proposed civil penalty are:

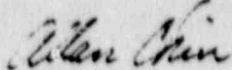
- 1) There was no prior warning of potential civil penalty.
- 2) There was insufficient time to prepare for the enforcement meeting.
- 3) There was never any threat to the safety of the public or workers.
- 4) RSI has been sensitized to the new level of compliance enforcement.
- 5) RSI has already been damaged in the medical market. Additional damages of significant magnitude could occur if the penalty is not totally mitigated.
- 6) RSI will be severely damaged in the food market if any penalty is levied.
- 7) A majority of the alleged violations are the result of misconceptions, misunderstandings and misinterpretations.
- 8) Several of the violations were a result of our attempt to improve our safety system.
- 9) RSI's prior inspection responses were tailored to

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meet existing enforcement sensitivity levels. We were unprepared for the recent change in sensitivity.

Based upon my 10 CFR 2.201 responses and those contained in this letter, I respectfully request that the proposed civil penalty be totally mitigated.

Respectfully,



Allan Chin
President

Enclosure

AC/sa

Appendix

NOTICE OF VIOLATION

Radiation Sterilizers, Inc.

License No. 04-19644-01

As a result of the inspection conducted on March 14, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

1. License Condition No. 19 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents.

The referenced January 21, 1981 application states that a monthly inspection of safety systems will be performed. The systems to be tested include radiation detection equipment, emergency devices and cell barriers.

Contrary to this requirement, the safety system inspections are not performed monthly and are oftentimes incomplete when they are done. Specifically, no safety system inspections were performed between October 1984 and March 1985.

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

2. License Condition No. 19 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents.

The referenced January 21, 1981 application states that the irradiator pool water will be tested for radioactive contamination after each source loading and at six month intervals thereafter.

Contrary to the above, a contamination test of the irradiator pool water was not performed promptly after a source loading in April 1983. Specifically, the test was not done until June 1983.

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

3. License Condition No. 19 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents.

The referenced January 21, 1981 application states that two radiation detection systems will be employed, one in the irradiation cell and the other in the cell maze.

WHY??

what does this mean

WHY

why - how
was this
out?

Contrary to the above, on the day of the inspection, only one radiation detection system was in use. The system located in the irradiation cell was not operable.

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

4. License Condition No. 19 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents.

why - how
was this
out?

The referenced January 21, 1981 application states a flashing warning light is automatically activated upon system startup.

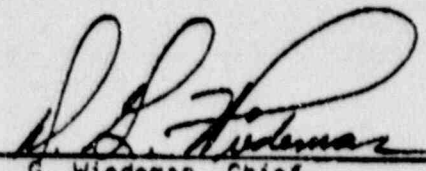
Contrary to the above, the warning light was not functional on the day of the inspection.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

MAR 28 1985

Dated _____


D. G. Wiedeman, Chief
Nuclear Materials Safety Section 1

Tom - why did the violations occur?
Send me a copy of your response.
Some of these indicate negligence
on your part - AL