NUREG--1392

TI90 007808

Leakage of an Irradiator Source -- the June 1988 Georgia RSI Incident

Manuscript Completed: September 1989
Date Published: February 1990

State Programs
Office of Governmental and Public Affairs
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Environmental Protection Division
Georgia Department of Natural Resources
205 Butler Street, S.E
Atlanta, GA 30334

ABSTRACT

On June 6, 1988, operators of a pool irradiator in Decatur, Georgia were prevented by a safety system from raising sources from the pool. Radiation levels of 60 millirem per hour at the surface of the pool water were found, indicative of a leak of one or more of the 252 Cs-137 source capsules used at the irradiator.

The irradiator had been originally licensed in 1984 by the State of Georgia to use Co-60 sources. In 1985, NRC announced it would accept applications for licenses to use Cs-137 sources supplied by the Department of Energy (DOE) for use in irradiators. In 1986, Georgia amended the irradiator license to use these capsules. The 252 Cs-137 capsules supplied by DOE were installed in the irradiator.

The 1988 leak resulted in licensee, and local, State, and Federal government efforts totalling several millions of dollars to identify and contain the contamination caused by the leak as well as isolate, remove and identify the cause of the leaking source. These efforts are still ongoing.

Because of the concerns which arose out of this incident, the State of Georgia and the Conference of Radiation Control Program Directors, Inc. decided it should be reviewed in depth.

Georgia Governor, The Honorable Joe Frank Harris, created an Incident Evaluation Task Force and charged it with collecting information on the incident, maintaining communications with the DOE Investigative Board and preparing a written report of lessons learned. Since the incident and response to it are still ongoing, a final report of the task force is expected at a later date. A summary of the Task Force's First Interim Report has been prepared for persons needing an overview of the incident and lessons learned to date.

The Conference established an Incident Review Team which agreed to assume the responsibility from the Georgia task force to discuss the role of the States in regulating irradiators. Its Interim Report provides a summary of Agreement States' views and recommendations on some of the issues raised by the incident.

The mention of commercial products or services in connection with this report is not to be construed as either an actual or implied endorsement of such products by the U.S. Nuclear Regulatory Commissions or other organizations responsible for this report.

CONTENTS

CONTENTS

U.S. NUCLEAR REGULATORY COMMISSION FORWARD

In 1959 Congress amended the Atomic Energy Act adding a new Section 274, "Cooperation With States." Among other things, this section permits NRC to relinquish its regulatory authority to qualified States to assert their authority over certain radioactive material users. Currently 29 States have entered into such Agreements and these States regulate 67% of the approximately 23,000 radioactive materials licensees in the United States. Responsibility within the NRC for administration of the Agreement State program lies with the State Programs of the Office of Governmental and Public Affairs.

The NRC and Agreement States routinely exchange technical and other information under these Agreements. These exchanges can include internal reports prepared by the States. The Conference of Radiation Control Program Directors, Inc. is a national organization of the program directors and staffs of State and local radiation control programs. The Conference works closely with NRC and other Federal Agencies having common interests in radiation protection.

Selected reports from these sources are published by NRC in its NUREG series because they cover events or regulatory activities that are of special interest to other regulators, to professional workers such as in the field of radiation protection, and to the public.

Carlton Kammerer, Director
State Programs
Office of Governmental and Public Affairs

SUMMARY - FIRST INTERIM REPORT

OF

THE RSI INCIDENT EVALUATION TASK FORCE

Prepared by:

James L. Setser, Chairman
RSI Incident Evaluation Task Force
June 30, 1989

1. SUMMARY-FIRST INTERIM REPORT OF THE RSI INCIDENT EVALUATION TASK FORCE

1.1 FOREWORD

Because of a considerable amount of concern which arose out of an ongoing incident at Radiation Sterilizers, Inc. (RSI) near Decatur, Georgia, Governor Joe Frank Harris created an RSI Incident Evaluation Task Force. The Task Force, comprised of both U.S. Nuclear Regulatory Commission and State of Georgia participants, was charged with: collecting all information possible about the RSI incident; establishing and maintaining communications with the U.S. Department of Energy's RSI Investigative Board; and, preparing a written report of "lessons learned" including any needed recommendations for future decision making on this type of incident.

The RSI Incident Evaluation Task Force has prepared a detailed report entitled, "First Interim Report of the RSI Incident Evaluation Task Force," which is based on information obtained through January 31, 1989. Because the RSI incident is still ongoing, a final report is expected to be issued at a later date. This Summary of the First Interim Report has been prepared for distribution to those individuals and organizations that only need an overview of the incident and lessons learned to date.

1.2 SUMMARY AND CONCLUSIONS

- The RSI-Decatur facility is one of approximately 140 commercial irradiators on a world-wide basis that sterilizes disposable medical products by gamma-ray sources.

- The RSI-Decatur facility is one of four licensed commercial irradiator facilities in the United States that uses cesium-137 (WESF capsules) as an irradiator source. (Two of the four facilities are owned by RSI.)

- The RSI-Decatur facility was licensed by the Georgia Department of Human Resources (DHR). The license and incorporated conditions are consistent with licenses issued to other commercial irradiators by the U.S. Nuclear Regulatory Commission (NRC).

- The WESF capsules are owned by DOE and leased to the commercial licensed irradiators in the United States.

- The RSI incident is still on-going; thus far, seven of 252 WESF capsules have been removed from the facility.

- Three of the seven capsules removed from the RSI-Decatur facility were found to be deformed and one of the three was confirmed to be a leaking source.

- The RSI incident is a high cost remedial/recovery action with costs already exceeding several million dollars to date. Although the costs associated with the RSI incident are currently being borne by DOE, the issue of ability to pay for recovery from an incident is applicable to the irradiator industry in general. Financial assurance requirements need to be examined as a part of overall regulatory reform in the irradiator industry.

- The State response costs for the RSI incident are not currently being borne by DOE. These "unplanned" State expenditures are significant with respect to operating budgets. The Conference of Radiation Control Program Directors, Inc. is reviewing the overall issue of cost recovery on a national basis and the results will be available at a later date.

- There is no evidence of any discharge to the environment nor any immediate threat to public health and safety as a result of the RSI incident.

- While there is some evidence of internal exposure to RSI personnel there is no evidence of overexposure or exceedance of any standards.

  RSI personnel inadvertently transferred Cs-137 contamination from a controlled area to other areas of the RSI building, to private homes of employees, and to one employee's automobile. All contaminated areas external to the RSI building have been decontaminated.

- One shipment of products, having exterior packaging contaminated with Cs-137, was allowed to leave RSI without knowledge that contamination was present. The shipment was recalled before it reached its destination and later disposed of at a licensed low-level radioactive waste disposal facility. No other contaminated products were detected outside of the RSI building. On the basis of the customer facility/products survey, it is reasonable to conclude that no contaminated products were released (except for the shipment that was recalled).

- The potential for contaminated packages is a serious matter for consideration in the operation of irradiator facilities. Public concerns can only be alleviated through strict accountability for assuring uncontaminated packages. Adequate monitoring systems must be put in place to provide such assurance.

- In the RSI incident, radioactive contamination of the pool water went undetected until it became high enough to involve a safety system which prevented the sources from being raised out of the water. If a sensitive "in-pool" monitor had been operational, the leaking capsule might have been detected much earlier. Consideration should be given to changing the regulatory regime to require "in-pool" monitoring on a continuous basis.

° Preliminary information supplied by the Chairman of the DOE Investigative Board indicates that WESF capsules, at the time of encapsulation, were never intended for use in commercial irradiators. A later DOE decision to use the WESF capsules for such a purpose was made over the objections of certain DOE staff.

° Serious questions have been raised about the validity of data used to arrive at a decision regarding capsule integrity. The relationships of the presence of impurities in the Cs-137 chloride, the "topping off" practice during encapsulation, and the impact of thermal cycling in a "wet load, wet storage, dry irradiator" mode require further investigation. The integrity of these capsules remains an unresolved issue at the time of this First Interim Task Force Report.

° The RSI incident has demonstrated that a strong and credible health physics program was not in place at RSI. If this is true because it was not required and it was not required because regulatory guidance does not promote it, then there needs to be a much stronger focus on health physics in the regulatory regime for commercial irradiators.

  The important lesson to be learned from this issue is that during the licensing of RSI and other irradiators, there has been little focus on the implications of a leak and thus some irradiator facilities have possibly not believed it necessary to provide a strong health physics program. Now that such a high-consequence event has occurred, a new regulatory focus on health physics programs for all irradiators should be considered.

° The RSI incident demonstrates the need for a potential regulatory requirement for an up-front detailed emergency response plan, submitted by facility irradiators, before a license is issued for either possession or use.

° Because of the impact of an RSI incident, there is a definite need for a Community Relations Plan. There are a number of mechanisms for causing such a plan to be created by the irradiator facility. One such mechanism that should be evaluated is the requirement for an overall Emergency Contingency Plan which includes a Community Relations Plan that can be activated by the facility when the need arises.

° Because the RSI incident has demonstrated that a low probability-high consequence event can, and does occur, the upgrading of training requirements for radiation safety officers and facility operators should be a significant focus in any regulatory reform.

- The commercial irradiator industry involves the operation of complex facilities that utilize significant amounts of radioactive material. When considering improvement areas in the regulatory reform process, an "early warning process" should be included, in order to allow more time for regulatory authorities to become familiar with the proposed activities of irradiators. This "early warning process" should be considered prior to the submittal of a completed license application for a facility. In addition, minimum review times and check points may need to be built into the license review process to negate pressure on regulatory authorities to issue the license in an expedited manner.

- The RSI incident has demonstrated the need for an improved communications system to provide complete, and timely information to parties which have a need to know. This system should be pre-established, tested, and supported such that it is ready for activation when an irradiator incident occurs.

1.3 BACKGROUND INFORMATION

1.3.1 Irradiator Industry

One of the major peacetime uses of nuclear energy that has evolved since the early 1960's is the use of fixed source irradiators to sterilize medical and pharmaceutical disposable supplies. The source of gamma rays used for sterilization is primarily from cobalt-60 and more recently, from cesium-137.

Since the first large commercial wet source type irradiator went on line in 1960, over 140 such facilities have become operational on a world-wide basis. There are currently 38 licensed irradiators in the United States and twenty of these have gone into operation since 1980. About 40 - 50% of all medical disposables are now being sterilized by gamma ray sources. In addition to the sterilization of medical disposables, the industry is also standing at the threshold of an even larger application market in the food industry, depending on decisions made by the Food and Drug Administration and the U.S. Department of Agriculture.

The possession and use of radioactive sources, used in commercial irradiators, is licensed by the U.S. Nuclear Regulatory Commission (NRC) in those States that do not have Agreement State status. For those States that have entered into a signed Agreement with NRC to license the use of certain categories of radioactive material, the irradiator license is issued by a State regulatory entity. The regulatory scheme has also evolved with the technology. As experience, incidents, improvements in technology, and needs have been identified, the regulations and guidance have been modified and in most cases, strengthened over the past several years.

While there are many well managed and carefully controlled irradiator facilities, there have been problems due to design, fires, and other license violations due to a lack of management commitment in the irradiator industry.

1.3.2 Cesium-137 as an Irradiator Source

Cesium-137 (Cs-137) is one of the major by-products of uranium-235 fissioning in spent fuel from power reactors, weapons reactors, and waste from certain other activities. In the 1960's and 1970's the only reprocessing of defense-related waste occurred at facilities owned by the U.S. Government. The result was a significantly large volume of liquid high level radioactive waste which contained, as one of its principal components, Cs-137. In order to reduce the volume of waste containing Cs-137, a program was established at the U.S. Government's Hanford Facility (now owned by the U.S. Department of Energy), near Richland, Washington, for extraction and encapsulation of the Cs-137. The Waste Encapsulation and Storage Facility (WESF) was established for removing the Cs-137 material from ion-exchange media, converting to a chloride form, and encapsulating in double walled stainless steel canisters, which were stored in a special temperature and water-chemistry-controlled pool on site.

Over a period of 17 years, about 1500 WESF capsules were filled and stored at the WESF storage pool in Hanford, Washington. Each capsule is 21 inches in length, 2.5 inches in diameter, and each wall thickness is 0.136 inches; and, a newly filled capsule contains approximately 50,000 curies of Cs-137.

In July 1978, the U.S. Department of Energy's (DOE) predecessor, the Energy Research and Development Administration, made a policy decision to depart from the original intent of the WESF program objectives. A course of action was established which ultimately led to the use of the WESF capsules in commercial irradiators. After many discussions, reviews, and negotiations between the U.S. NRC and DOE, the first commercial facility to use WESF capsules was licensed by NRC on April 8, 1985. The irradiator, owned by Radiation Sterilizers, Inc. (RSI) in Westerville, Ohio, was licensed to use 8.2 megacuries of Cs-137, encapsulated in a total of 180 WESF capsules, leased to the RSI by the U.S. DOE. The license allowed a "wet load, wet storage, dry irradiator" mode of operation. In this mode the WESF capsules are transferred from the shielded shipping container under water; suspended under water while not being used for sterilization; and, raised from the storage pool to the air above the pool during product sterilization.

A second commercial irradiator (Iotech, Inc.) in Northglenn, Colorado was licensed by the State of Colorado for use of WESF capsules on June 14, 1985. Since that time, two additional facilities were also licensed to use Cs-137 in 1986. These are located at RSI in Decatur, Georgia and the Applied Radiant Energy Corporation in Lynchburg, Virginia.

1.3.3 Radiation Sterilizers, Inc. (RSI)

As was previously mentioned, RSI facilities currently hold two of the four radioactive material licenses for the use of WESF (Cs-137) capsules as irradiator sources. The RSI facility in Decatur, Georgia is the focus of this Task Force Report.

RSI is a privately held California corporation which was incorporated on August 29, 1978. In addition to its corporate offices near Fremont, California, RSI's business is conducted at five branches located in: Schaumberg, Illinois; Tustin, California; Westerville, Ohio; Decatur, Georgia; and Fort Worth, Texas. The primary business operations consist of:

(1) provision of radiation sterilization services to the health care industry;

(2) provision of radiation processing services to food and other industries;

(3) design and installation of radiation facilities for manufacturers whose product volumes create a need for in-house processing;

(4) provision of contract filling of cans of nitrogen aerosol-dispensed contact lens solutions.

The RSI Decatur facility is located in the Snapfinger Woods Business Park, about 20 miles east of Atlanta, Georgia in DeKalb County. The facility consists of a 21,000 square foot brick building, of which 4,000 square feet are devoted to the radiation cell area and 1,600 square feet to administrative office space. The remainder of the building is divided into two physically separated areas for irradiated and non-irradiated products.

The radiation cell is composed of the concrete gamma cell room (6 ft. thick concrete walls) and a maze system (4 ft. thick concrete walls) which leads into the gamma cell. The gamma ray source initially used at RSI-Decatur was cobalt-60 (500,000 curies). This was replaced in 1986 with 12.3 megacuries of Cs-137 in a total of 252 WESF capsules leased from the U.S. DOE. The facility which was licensed by the State of Georgia (Department of Human Resources) is operated in the "wet load, wet storage, dry irradiator" mode. The storage pool in the source operations room is a 25,000 gallon tank of demineralized water, contained in a stainless steel lined concrete structure approximately 6 feet wide by 24 feet long by 24 feet deep. The WESF capsules are stored in two racks on opposite sides within the pool. The uppermost row of capsules in a rack is approximately 12 feet below water level.

During sterilization operations, the racks are raised out of the pool by electric winches located on the roof of the facility's concrete gamma cell. In the raised position the panoramic radiation effectively destroys all microorganisms on the products, which are passed through the gamma cell on a conveyor system. Dosage levels are a function of the conveyor speed and the activity of Cs-137 in source racks. The conveyor system utilizes "totes," or metal containers, to transport the product around the source. RSI utilizes a product overlap design in which the conveyor system causes the source to be surrounded by the product. The conveyor system is controlled by programmable controllers which are interconnected with diagnostic computers that monitor all conveyor functions.

The safety system at the RSI-Decatur facility, which is supposed to preclude accidental radiation exposure to personnel, has detectors connected in series. A violation of any one detector will cause the system to shut down automatically. These detectors include photocells, pressure mats, radiation level monitors, seismic sensors, smoke detectors, and temperature sensors.

In addition to the radioactive materials license, RSI-Decatur is also registered with the Food and Drug Administration under Device Master File Number MAF122, Drug Master File Number DNF5807, and registration number 1037726.

1.4 RSI INCIDENT DESCRIPTION

1.4.1 Initiating Events

On June 6, 1988, RSI-Decatur notified the Georgia Department of Human Resources (DHR) that some event had occurred which resulted in the automatic lock-in-place of the source system under water. Preliminary measurements showed higher than normal radiation levels at the surface of the pool. Discrete samples of pool water were collected and analyzed in the radiochemistry laboratory at the Georgia Institute of Technology. The analytical results showed elevated levels of Cs-137 dissolved in the pool water. This indicated that one or more of the 252 WESF capsules had become breached and thus, cesium-137 chloride was being transferred from the interior of the capsule to the water where it was dissolving.

Since this was the first recorded instance of a leaking WESF capsule, a joint federal/state task force, consisting of the Georgia Department of Natural Resources (DNR), the Georgia Department of Human Resources (DHR), and the U.S. Nuclear Regulatory Commission (NRC), was established to assist with the RSI incident.

After review and recommendation by the joint task force and upon discussions with RSI, on June 11, 1988, the State of Georgia formally requested that the U.S. Department of Energy manage an effort to identify the leaking capsule; develop a plan for the safe removal of the leaking capsule; manage the removal of the damaged

source; and oversee the cleanup and recovery activities at RSI. The U.S. Department of Energy (DOE) responded immediately to the State of Georgia's request and dispatched resources from its Oak Ridge Operations Office to the RSI site near Decatur, Georgia. Additional resources from the Westinghouse Hanford Corporation, a contractor to DOE, and from Chem Nuclear Systems, Inc., a contractor to RSI, have since mobilized at the RSI facility. The joint federal/state technical assistance task force was also expanded to include representatives from the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).

1.4.2 Environmental Monitoring Activity

Resources from the Georgia Department of Natural Resources mobilized at the RSI site. A mobile laboratory and communications center was placed into operation outside the RSI building. A detailed environmental survey was completed in which both direct readings, continuous sampling, and analyses of discrete soil and air samples were made. Additionally, samples of drinking water, sewer water, grass samples, and air vent smears were analyzed. No detectable cesium-137 radioactivity was measured in any of the samples or by direct instrument surveys outside the RSI building. Continuous air monitoring has been in effect since DNR moved onto the site. A detailed Environmental Monitoring Plan was written and is being implemented concurrent with on-going operations within the RSI building. Because cesium-137 radioactivity was not detected outside the building, a "no-threat-to-the public" conclusion was reached and the media, as well as surrounding business representatives in the Snapfinger Woods Business Park, were so notified.

1.4.3 RSI Personnel Evaluation

A total of 43 personnel were employed at the RSI facility at the time of the incident. Ten of these people were identified by RSI management as working in or near the source area. These employees were evaluated for the presence of radioactive contamination by a team of DHR, NRC, and RSI representatives. This evaluation consisted of the following:

(1) Film badges worn by employees were developed in an expedited manner. All results showed normal exposure levels.

(2) Blood samples were taken from each of the employees by qualified medical staff and the results did not reveal any abnormal charactreristics.

(3) Urine samples were collected and sent to a qualified bioassay laboratory for analysis. The results showed that cesium-137 levels were well below allowable standards.

(4) Detailed surveys of the automobiles, clothing, and residences of the ten employees were conducted by DHR personnel. The survey results showed that the areas associated with seven employees were free of cesium-137 contamination. One of the three remaining employees was found to have measurable radioactive contamination in his private automobile, and the other two persons were found to have contamination on their residence carpets and on certain articles of clothing. All contaminated items were removed and stored within the RSI facility. The low-level radioactive waste was later shipped to Barnwell, S.C. for disposal in an approved low-level radioactive waste disposal facility.

1.4.4 Product Monitoring

After a review of the RSI operating records and consideration of other factors, April 29, 1988 was established as the last known "clean" operating date at the RSI facility. RSI management made immediate notification to the distribution warehouses to hold all products shipped to them during the period April 29 through June 5, 1988 that had not already been distributed to their customers. The U.S. Nuclear Regulatory Commission coordinated with the cognizant State radiological health agencies to survey all the packages at the distribution centers in the United States and Canada. All surveys were completed and all packages were found to be free of radioactive contamination. However, one transport vehicle still in the Atlanta area ultimately destined for a Jacksonville, Florida warehouse was recalled by RSI and surveyed at the RSI facility. The results showed pinpoint contamination on the exterior surfaces of several shipping containers. After a confirmatory survey by the State of Georgia, a final decision was made by RSI management, and concurred in by the Food and Drug Administration staff, to dispose of them as radioactive waste.

1.4.5 Preliminary RSI Building Survey and Decontamination

An extensive survey of the RSI building was conducted by the Chem Nuclear Systems, Inc. staff. Confirmatory surveys were also conducted by the Georgia Department of Human Resources. Areas contaminated with Cs-137 were identified throughout the interior of the building, including the carpet in the administrative area. Access to the RSI building was placed under the control of Chem Nuclear System, Inc. with the concurrence and support of RSI management, DOE site management, and the State of Georgia. Procedures were implemented for restricted access by only identified and authorized personnel. A slow deliberate process of identification and removal of contamination was initiated while other contractor personnel began the development of detailed plans for evaluating and removing the damaged source(s). The process of building decontamination is still ongoing at the time of preparation of this Task Force Report.

1.4.6 Pool Water Decontamination

During the first week of the RSI incident, measurements of source pool water showed that approximately 4 curies of Cs-137 radioactivity was dispersed throughout the 25,000 gallon tank of water. Chem Nuclear Systems, Inc. placed shielded demineralizer columns in operation to reduce the level of Cs-137 radioactivity in the pool. It was necessary to reduce the levels in the pool so that examination of the WESF capsules could begin, and so that the entry level of Cs-137 from the damaged source(s) to the pool could be established.

The leak rate from the damaged source(s) remained nearly constant at about 25 microcuries per hour until the period October 7-12, 1988. For some undetermined reason, the Cs-137 entry rate to the pool increased to over 600 microcuries per hour, then decreased over the next several days to about 150 microcuries per hour, at which level it remained until November 29, 1988. On this date a leaking WESF capsule was identified and isolated in an overpack container. The Cs-137 entry rate then dropped rapidly to less then 40 microcuries per hour.

1.4.7 Source Evaluation

An underwater visual examination and ultrasonic testing was conducted for all 252 source capsules. Twenty-nine of the source capsules were designated as "suspect" due to abnormal discoloration in the vicinity of the welds at the end caps on the cylinders. The twenty-nine "suspect" capsules were again evaluated by using an ultra-sonic probe technique. Two of the capsules displayed a wave pattern which indicated the presence of water between the inner and outer cylinder walls. An underwater weighing procedure was also initiated but was discontinued because of lack of confidence in the results by investigators. In order to conduct additional evaluations of the suspect capsules, three capsules were removed and tested in a controlled facility at Oak Ridge Operations. Since it was determined that the damaged source(s) still remained within the pool, the U.S. DOE fabricated a special test device to isolate the leaking source(s). The special test device, known as a pressure cycle leak detector ("six pack sipper"), was placed in the pool at RSI-Decatur in early November 1988, and, for the next two weeks underwent a series of operational tests. Actual capsule testing began on November 13, 1988, with a projected completion schedule of December 20, 1988, for the remaining 249 WESF capsules. On November 29, 1988, test operators noted that Capsule No. 1502 would not fit into the sipper device. Upon detailed visual examination by an underwater camera it was discovered that a quarter-inch bulge near the end of the capsule was the problem. The capsule also appeared to have a visible crack perpendicular to the weld seam, which extended along the body of the capsule for several inches.

The capsule was isolated in an overpack, and over the next 24 hours the Cs-137 level in the pool declined significantly. Later, a discrete water sample, collected out of the overpack, showed a highly elevated Cs-137 level, further confirming that Capsule No. 1502 was a "leaker." On December 3, 1988, another capsule, No. 1504, was also observed to have a bulge similar to Capsule No. 1502, but there was no visible evidence of a fracture. This capsule was also isolated in a second overpack container in the pool.

1.4.8 Removal of Sources

As of the date of this First Interim Report, five WESF capsules have been removed from the RSI-Decatur facility and transferred to DOE Oak Ridge Operations for nondestructive evaluation. The first source capsule was removed from its rack in the pool and placed inside a special fabricated stainless steel overpack. Attempts were made to remove all water inside the overpack with a nitrogen gas purge. The overpacked source was placed in a General Electric Type 600 shipping cask which was placed inside the pool by crane through the roof of the building. The shipping cask was removed and placed on a DOE transportation trailer. It was transported to Oak Ridge on August 17, 1988. Upon arrival, it was noted that the overpack contained several milliliters of water and thus the container had to be redesigned before shipping any other capsules.

On September 16, 1988, two additional capsules, that had previously demonstrated positive ultrasonic wave patterns, were removed and transported to Oak Ridge in the same manner as the first capsule. It was confirmed that they were not leakers.

Two capsules that were transported to Oak Ridge for evaluation on December 20,1988, were the two (Nos. 1502 and 1504) that showed evidence of a bulged condition. Capsule No. 1502 also exhibited characteristics of a leaker. Later evaluation by DOE at its Oak Ridge Operations facility confirmed that No. 1502 was a leaking capsule. Capsule No. 1504 was found to be bulged but not leaking.

1.4.9 Transportation of Remaining WESF Capsules

At the present time a plan for removal and shipment of the remaining 245 WESF capsules to the DOE Hanford Facility has been established and shipment is expected to begin on May 29, 1989.

1.5 FINDINGS OF THE TASK FORCE

1.5.1 Overview

The RSI incident Evaluation Task Force has spent a considerable amount of time reviewing records of the Incident; reviewing file

documentation of past U.S. Nuclear Regulatory Commission and U.S. Department of Energy proceedings; having informal discussions with federal and State personnel associated with the incident; reviewing of testimony from special interest groups and interested parties at a formal public hearing; and having formal meetings of the Task Force Members at which indepth discussions of the issues were held with the Chairman of the U.S. DOE Investigative Board for the RSI incident.

In reviewing the information available and developing the primary issues for consideration in the First Interim Task Force Report, it should be noted that three important events have not yet occurred at the time of preparation of this Report. These events are:

° The recovery from the RSI incident is still ongoing. Only seven of 252 WESF capsules have been removed from the RSI-Decatur facility and decontamination procedures are still in progress.

° Although the U.S. Department of Energy created a special RSI Incident Investigative Board to determine the cause of the RSI incident, the investigations by this Board are incomplete and a written report has not been issued as of the time of preparation of this First Task Force Interim Report. All preliminary findings and conclusions of the Board referenced in this Task Force Report are a result of oral communications with the Chairman of the DOE Investigative Board.

° Two damaged WESF capsules were removed, one of which was confirmed to be leaking, and have undergone preliminary non-destructive examination at DOE's Oak Ridge Operations. Because destructive evaluation has not yet been completed as of the time of preparation of this First Interim Task Force Report, a formal conclusion about the cause of damage to the WESF capsules has not yet been reached by DOE.

In general, the issues developed by the Task Force can be grouped into four broad areas, as follows:

(1) Issues related to source encapsulation, source testing, and decision making associated with the use of WESF capsules in commercial irradiators. (SOURCE ISSUES).

(2) Issues related to the initial response to the RSI incident, notification, communications, and overall handling of the incident. (RESPONSE ISSUES).

(3) Issues related to RSI in-house operations, health physics, monitoring, and recordkeeping. (RSI OPERATIONS ISSUES).

(4) Issues related to licensing and/or regulatory reform.

Before discussing the specific issues under each of the proceeding broad categories, three overall points of interest need to be highlighted: (a) the RSI incident falls into the descriptive category of a "low probability, high consequence event"; (b) there is no evidence of any release of radiation to the environment, as a result of the RSI incident; and (c) there is no evidence that any immediate threat to public health and safety occurred during the RSI incident.

1.5.2 Source Issues

1.5.2.1 Intended Use of WESF Capsules

The WESF capsules were created out of a process geared toward waste volume reduction, and they were not intended for use in an irradiator facility when initially fabricated. According to the Chairman of the DOE Investigative Board, there is evidence that strongly suggests that the program staff that carried out the encapsulation procedures expected the WESF capsules to remain stored in the temperature and chemistry-controlled pool at the Hanford Facility for a long indeterminate period of time. The encapsulation techniques, quality control, and degree of recordkeeping were all predicated on the expectation that the capsules would remain in a "benign environment." The use of WESF capsules in a "wet load, wet storage, dry irradiator" mode of commercial irradiator operation was never envisioned during encapsulation.

There is documentation in the encapsulation records of a "topping off" practice in filling capsules with molten cesium-137 chloride. In other words, after filling a batch of six capsules, there was only enough molten material left to partially fill a seventh capsule. This capsule was partially filled and allowed to sit aside until another batch of melt was prepared, which was in some instances, several days. The partially filled capsule would then be "topped off" and capped, potentially creating an internal pressure condition due to later expansion under elevated temperatures. DOE's examination of the encapsulation records revealed that WESF Capsule Nos. 1502 and 1504, removed from the RSI-Decatur facility and determined to be bulged, were fabricated as part of the same batch of seven in 1982. Capsule 1502, the confirmed leaking capsule, is also one of those capsules that was "topped off" in the encapsulation process.

During the encapsulation process, documentation on the visual presence of impurities in the cesium-137 chloride melt, as determined by visual examination, was placed in the records when such impurities were observed. In reviewing later tests that were conducted on some WESF capsules, the records reflect that there are data which indicate an enhanced capsule corrosion problem in the

presence of impurities. Whereas no conclusion has been formulated about the relationship of the presence of impurities to the cause of the RSI incident, records do exist that show WESF capsules with impurities are included in the irradiator sources at all four licensed facilities that use Cs-137. The integrity of these capsules thus remains an unresolved issue at the time of this First Interim Task Force Report.

1.5.2.2 Adequacy of Data to Support Use of WESF Capsules in the RSI Mode of Operations

The testing of the WESF capsules includes: (a) operational use and post evaluation from a DOE irradiator, (Sandia facility) - (wet load, dry storage, dry irradiation mode of operation); (b) mechanical testing (impact, percussion, and fire); and (c) on-line operating experience at RSI's Westerville, Ohio and Decatur, Georgia facilities.

According to the Chairman of the DOE Investigative Board for the RSI incident, the Board is still reviewing the available information on testing but it generally appears that the testing was conducted by one or more individuals within DOE who had an inherent strong desire to see the WESF capsules licensed for use in a commercial irradiator. Further, questions and concerns raised at the time by others in the DOE organization were overridden by those who supported going forward with the use of the WESF capsules in commercial irradiators. While there were individual structural tests conducted to evaluate compliance with ANSI standards (American National Standards for Sealed Radioactive Sources, N542), there is no indication that synergistic testing was conducted. As an example, a capsule was heated to high temperature and allowed to cool, and a different capsule was dropped on a pointed surface, but a single capsule was not simultaneously heated to 800 degrees centigrade and then dropped in this condition through cold water onto a pointed surface. There now exists an open question about bias of the test results and whether they reflect an accurate picture of a psule integrity. The record does reflect the positive, successful use of the WESF capsules at the Sandia facility under a "wet load, dry storage, dry irradiator" mode of operation. This mode of operation was different from the RSI mode of operation which involves source cycling from water storage to air irradiation and back to water storage again.

A review of the files shows that NRC and DOE negotiated an agreement over a two-year period for the implementation of an irradiator demonstration project which would utilize WESF a psules in the "wet load, wet storage, dry irradiator" mode of operation. The key component of the "agreement" was the removal of a capsule, after at least one year of operation and evaluation of that capsule by DOE to

determine any adverse effects before licensing another commercial irradiator to operate in the same mode. RSI's Westerville, Ohio facility was chosen for the demonstration project. Less than one month after the WESF capsules were installed at the RSI-Westerville facility, DOE requested that NRC review its position on wet storage irradiators and about six weeks after the DOE request, NRC formally decided that the Agency would consider other license applications for WESF capsules. The basic issue relates to whether or not there were adequate test data provided to NRC by DOE to justify the departure from the original agreement.

The perception of the Chairman of the DOE Investigative Board is that NRC relied on the information and recommendations provided by DOE about c psule integrity. The same DOE staff that provided this information was unable to envision or accept the possibility of capsule failure and thus, they were zealous in pursuing NRC approval. In a sense, they convinced the NRC technical staff that there was no need to wait at least a year on the demonstration project before licensing any more irradiator facilities to use WESF capsules because capsule failure was such a low probability. The Chairman of the DOE Investigative Board expressed the view that NRC, as an independent regulatory agency composed of a highly technical staff trained in the scientific reasoning process, should not have just accepted the DOE data as provided but should also have conferred with the people who actually encapsulated the WESF capsules.

NRC's position is that it allowed the Georgia facility to be licensed before the "one year agreement." The key component of the agreement was thermocycling. Thermocycling was thought to be the weak link in all operational failure scenarios. Therefore, since the Ohio facility was in opeation first, it would always have more thermocycles than any facility licensed at a later date; consequently, any failure would occur there first. NRC departed, however, from normal procedures and did not add the WESF capsule to its registry of approved sealed sources; instead it notified NRC staff and agreement states that the WESF capsules were acceptable for licensing.

1.5.3 Response Issues

1.5.3.1 Initial Response to the Incident

Following notification of the State of Georgia by RSI that the source mechanism at the RSI-Decatur facility was locked into position, such that it could not be raised out of the water, it is pertinent to examine the adequacy and timeliness of the State response to the incident. Specifically, the issue relates to the

recognition of the magnitude of the situation and whether effectiveness in dealing with it may have been compromised as a result.

After an independent review of the response actions, the Task Force has concluded that while the Georgia DHR radiological responders and potentially others did not recognize the magnitude of the RSI incident during the initial two days, there are not any identified impacts on public health and safety because of such potential failure. The record reflects that the most experienced staff of the Georgia Radiological Health Unit was dispatched to RSI; the advice of a highly respected nuclear consultant was sought early on; and requests for information were made of RSI. Also, the DHR radiological staff issued an amendment to the RSI license which prohibited RSI from any further operation of the irradiator for sterilization because of a leaking capsule.

During the first two days of the initial response to the RSI incident, there was some criticism about inadequate communication, regarding incident details, between the State of Georgia and senior management officials at both DOE and NRC Headquarters in Washington, D.C. Because there had been no prior experience of an incident of this magnitude in Georgia, during the first two days of the incident there was an apparent failure to recognize the potential implications of the incident and the need to communicate information to DOE and NRC. As a result, incomplete information was provided. NRC decided that the definite scope of the problem had not been determined. As communications escalated to a high level between the agencies, "overly conservative conclusions" were reached and actions were ordered to be taken at local level. The lesson to be learned from this process is the need for a pre-established, tested, and supported communications system that automatically provides correct and timely information during an incident to those that have a need to know. Also, an emergency response plan which incorporates criteria and protective action guidance (PAG's) for irradiator incidents/accidents should be developed.

The joint federal/State team of two Georgia State Agencies and four federal agencies (DOE, NRC, EPA, and FDA), once established, provided direction, and functioned in an efficient, timely, and effective manner in handling the initial response to the RSI incident. However, in considering how the response might have been improved, it may have been possible to utilize additional sources of experience such as technical staff from Iotech, Inc. and Applied Radiant Energy, Inc., the other two licensed WESF capsule facilities.

1.5.3.2 Product Monitoring

Shortly after the recognition of the problem at RSI and initial notification to the State of Georgia, RSI management notified distribution warehouses of the potential for contaminated packages and requested that all products be held, without distribution to customers, pending further notification.

The RSI-Decatur facility source storage pool was last analyzed for Cs-137 radioactivity by discrete sampling on April 29, 1988 which was 37 days prior to the discovery of the pool contamination problem on June 6, 1988. Therefore, a decision was made by the response team to establish April 29 as the "last clean day" and to evaluate all remaining products processed and shipped from RSI-Decatur after that date.

RSI provided a computerized printout which listed the following information: date product was received at the RSI facility; date loaded for sterilization processing; customer identification code, process run number, quantity of product; and date of shipment. This information was used to conduct surveys at customer locations that received potentially contaminated packages. The information provided showed that some of the products still remained at the RSI-Decatur facility (on-site), and in addition to Georgia locations, the product had been shipped to locations in the States of Alabama, Florida, Michigan, Missouri, South Carolina, Tennessee, and Texas. Product had also been shipped to one international location in Canada.

The U.S. NRC coordinated the efforts of NRC staff and Agreement State teams that were dispatched to the various locations to which the products had been shipped outside of Georgia. Surveys of the Georgia locations, all in the metropolitan Atlanta area, were conducted by the DOE Interagency Radiation Assistance Program team from the Savannah River Reservation. Georgia DHR and NRC were also represented on each team. The survey teams used accepted health physics procedures in not only monitoring product cartons, but also in becoming cognizant of the receipt, flow, storage, and use of the cartons. All areas, equipment, and personnel were included in the surveys. At each facility, a survey was performed at the loading docks (receiving area), storage areas, process areas, and of equipment used such as fork lifts, carts, mops, and brooms. Surveys were also performed of floor drains and restrooms when appropriate. In addition to "direct reading" radiation measurements with portable instrumentation, smears were also collected which were later counted in the laboratory.

After all surveys were completed, the results showed that the only contaminated packages leaving the RSI facility that were observed were in product shipment, No. LLD-8013-D, which left the RSI-Decatur facility on June 6, 1988 en route by truck to Jacksonville, Florida. The shipment, which consisted of 7765 cartons on 13 pallets, was recalled immediately by RSI before it left the State of Georgia. Surveys were conducted at RSI-Decatur after the truck returned and pin-point contamination, showing elevated levels of Cs-137, were found to exist on the exterior surfaces of the shipping containers. The entire amount of product was later disposed of at the low-level radioactive waste disposal facility in Barnwell, South Carolina.

Results of the customer facility/products survey indicate that it is reasonable to conclude that no contaminated products were released (except for the one shipment that was recalled).

1.5.4 RSI Operations Issues

1.5.4.1 Transfer of Cesium-137 Contamination by RSI Employees

Monitoring activities conducted by the Georgia Department of Human Resources after the RSI incident began showed the presence of Cs-137 contamination in employees' homes, clothing, and an automobile. In addition, there was Cs-137 contamination of both production and administrative areas outside of the concrete gamma cell, but within the RSI-Decatur facility. The issue relates to the adequacy of and RSI management philosophy as to the need for a health physics program sufficient to detect contamination on employees before they leave a controlled area.

The first and foremost priority of RSI management should have been of concern for the public and its own employees. The development, implementation, and maintenance of a system to detect contamination before it leaves a controlled area is not only essential but should be something for which senior management holds subordinate staff specifically accountable. When the proper management attention and attitude are not present, regulatory authorities characterize the situation as a "breakdown in management control." Since personnel were allowed to leave a controlled area at the RSI-Decatur facility with undetected radioactive contamination, it must be concluded that either systems were not in place to detect the radiation or they weren't used effectively.

Whereas there are no data to show that RSI employees inhaled or ingested radioactive contaminants that exceeded standards, one employee did show evidence of a somewhat elevated level of Cs-137 in upper torso and in urine.

The important lesson to be learned from this issue is that during the licensing of RSI and other irradiators, there has been little focus on the implications of a leak and thus some irradiator facility owners/operators have possibly not believed it necessary to provide a strong health physics program. Now that such a high consequence event has occurred, a new regulatory focus on health physics programs for all irradiators should be considered.

1.5.4.2 Adequacy of Pool Water Monitoring Systems

The RSI incident was first brought to the attention of the facility operator by the functioning of a safety system which locked the source system in a stationary position. The safety system incorporates a radiation monitor which had a preset radiation level trip point such that when this level was exceeded the system would perform as it did. The monitoring system was operated in such a manner as to detect an increase in the radiation level when the sources were in the stored position.

Whereas a radiation detector is a part of the system design, it is not an in-line pool water monitoring system. The radiation detector is positioned adjacent to an external demineralizer column. The theory of operation is that as the pool water is recirculated through the demineralizer the detector would detect any increased level of radioactivity in the pool water. However, the records show that the pool water was not continuously circulated through the demineralizer. The demineralizer was used only when the pool water conductivity exceeded an established value, or when make-up water was added to the pool. Therefore, the Ginger-Mueller (GM) detector was not monitoring the condition of the pool water continuously. Since discrete samples of water were only analyzed periodically, small increases in pool water contamination over a period of time would go undetected. In the RSI incident it was just circumstance that allowed investigators to narrow the potential contamination period to only 37 days. There was a discrete pool water analysis on April 29, 1988 which showed that there was not an elevated level of Cs-137 in the water at that time. This became the basis for the decision regarding the subsequent survey and/or recall of sterilized products. However, if the last recorded discrete pool water analysis had occurred at a much earlier date, the magnitude of the product situation could have been very different.

Technology is available to install an in-line pool water monitoring system so that any small release of radioactivity into the pool, due to a leaking source, could be detected. Such a monitoring system was put in place at the RSI-Decatur facility by the DNR and DOE site recovery team. The system routinely detects a Cs-137 level of 2×10^{-7} microcuries per milliliter. This can be contrasted with 4×10^{-2} microcuries per milliliter in the pool water on June 6, 1988 when RSI discovered the problem.

1.5.4.3 Product Monitoring Before Leaving the Irradiator Facility

Whereas there is no record of contaminated shipping containers reaching a distribution facility, products contaminated with Cs-137, that were processed at the RSI-Decatur facility, were taken from a controlled area and loaded onto a truck which left the facility. RSI employees did not know that the packages were contaminated with Cs-137 on the outside surfaces. From both a professional health physics perception and a public perception, that condition is unacceptable.

The common thought and expectation pattern that is evident from the initial decision-making process to use WESF capsules in commercial irradiators, through the license issuance, and manifested within the facility management operations is the belief that WESF capsules would not develop a leak. Therefore, a health physics and/or monitoring program was not put in place to detect contaminated products before leaving the facility. The lesson to be learned from the RSI incident is that all involved parties need to think beyond the experience of the past and plan for reacting to the consequences. Public concerns can only be alleviated through strict accountability for assuring uncontaminated packages. Adequate monitoring systems must be put in place to provide such assurance. There is a precedent, experience, and/or rationale for such monitoring that can be found in the kinds of monitoring systems already in place at scrap metal yards, furnaces, some landfills, and other industrial operations.

Although changes in the regulatory program may be required to provide the proper incentive to irradiator management to recognize their own liability and need for accountability, common sense should prevail in the irradiator industry. Irradiator senior management should want and put such accountability in place, both for their own protection and assurance to the public.

1.5.4.4 Adequacy of Recordkeeping

In reviewing the "hard copy" operating data records at RSI-Decatur, there is a minimum of information. The basic issue relates to the adequacy of the information needed to track operating parameters, not only to comply with the radioactive materials license, but also to satisfy sound mangement practices that should have arisen out of the realization that there was very little operating experience with the use of the WESF capsules in the RSI mode of operation.

The operating records do contain check lists and handwritten notations of a noncontinuous nature about operations. However, there is an absence of consistent, detailed, and well-documented monitoring information, incident reports, and other data that might be used by an investigator to define the operating history character.

1.5.5 Licensing/Regulatory Reform Issues

1.5.5.1 Contingency Resource Availability for Handling a Leaking Capsule

During the licensing process, the Georgia Department of Human Resources (the cognizant regulatory agency) raised the issue of a potential leaking capsule with RSI and requested information on how such a leak would be handled if it occurred. RSI provided information at that time to the State of Georgia which substantially indicated that DOE already had equipment which would be used to identify, isolate, and contain a leaking WESF capsule. RSI stated that equipment already in existence at the DOE Hanford Facility, or similar, would be used to detect a leaking capsule and isolate it.

According to information from the Chairman of the DOE Investigative Board and from Westinghouse staff who came to RSI during the week of June 6, 1988, such equipment did not exist, at least for that purpose. Equipment was under development in conjunction with the specific Hanford WESF Facility design but the equipment, when completed, would be incapable of being transported and thus was clearly unusable as stated by RSI in reply to Georgia DHR's request for information. In addition, there were no written agreements or other agreements that have been found between DOE and RSI to substantiate the RSI contention.

The statement made by RSI may need to be considered for its "material fact" significance as part of the regulatory process for approving the use of the WESF capsule. However, the bigger issue of a potential regulatory reform nature relates to the need for detailed and up-front emergency response plans, submitted by facility irradiators before a license is issued for either possession or use.

1.5.5.2 Integrity of the RSI-Decatur License

The RSI-Decatur license was issued by the Georgia Department of Human Resources in its capacity as an Agreement State. The basic issue is the integrity of the license and whether it is indicative of the best professional practice and guidance available at the time of issuance.

The RSI license application was reviewed, prior to issuance of the license, by both the Georgia Department of Human Resources and the U.S. Nuclear Regulatory Commission. The criteria used to evaluate the application included: NRC Guide for the Preparation of Applications for Licenses for the use of Gamma Irradiators (proposed

Revision-1 to Regulatory Guide 10.9, April 1982); ANSI Standard, N43.10 (1984), entitled "Safe Design and Use of Gamma Irradiators"; and Georgia DHR's Radioactive Materials Rules and Regulations, Chapter 290-5-23, effective July 12, 1982.

In accordance with statements offered by U.S. NRC representatives and consistent with the record, the Georgia DHR incorporated the NRC guidance into the license issued to RSI-Decatur. The license issued to RSI-Decatur for the possession of 12.3 megacuries of Cs-137 on January 6, 1986 reflects professional practice in effect at that time. The license and incorporated conditions are consistent with licenses issued to commercial irradiators by U.S. NRC and one other Agreement States.

1.5.5.3 Adequacy of Training Requirements

In reviewing the training requirements specified by the Georgia DHR in its regulatory role and by other regulatory authorities in other States, most of the training required for the irradiator operator and/or radiation safety officer involves vocational-type training and on-the-job training. For instance, the Georgia DHR training criteria, which are consistent with those of other states, require that the radiation safety officer complete 20 hours of basic orientation training, 20 hours of intermediate training (includes conveyor operation, safety system, general operating procedures, emergency procedures, and radiation safety rules), 20 hours of advanced training (radiation dose evaluation, radiation protection procedures, instrument/detector theory, etc.), and a one-week University level course in radiation protection. There are not any requirements for any other academic qualifications.

The training required for large scale irradiator personnel may promote a level of experience needed to operate the irradiator system when all operations are routine; however, it may not be sufficient to recognize a significant radiation problem and/or take the necessary actions to contain the problem before it escalates. This was demonstrated by the RSI incident whereby personnel were contaminated and left a controlled area and contamination was spread from a controlled area to other areas in the building and contaminated products were allowed to leave RSI. Thus, the training and experience of the health physics personnel at RSI must be brought into question. The issue is broader than just RSI. Because of the complexity and significant amounts of radioactive material used in the commercial irradiator industry and recognizing the fact of a low probability-high consequence event, the upgrading of training requirements should be significant focus in any regulatory reform.

1.5.5.4 Ability to Pay for Recovery Operations

According to information contained in RSI's Audited Financial Statement, the company is self-insured with respect to general liability coverage. Whereas the specific issue of liability for the RSI incident has not yet been determined, the recovery costs are estimated to be in the multimillion dollar category to date. This raises the overall question of the ability of the company to pay for remedial action and recovery operations should a later decision fix liability with RSI for the incident.

Even though the RSI incident has been the most expensive one to date in the irradiator industry, there have been other incidents that have resulted in a significant expenditure of money, one of which involved about two million dollars. Therefore, the issue of ability to pay for recovery from an incident is applicable to the irradiator industry in general. Financial assurance requirements need to be examined as a part of overall regulatory reform in the irradiator industry.

1.5.5.5 Cost Recovery

The RSI incident has strained the resources of all participants significantly. Although the U.S. Department of Energy is paying for its own personnel and that of its contractors involved in the incident, the State of Georgia, U.S. Environmental Protection Agency, U.S. Nuclear Regulatory Commission, Food and Drug Administration, and the DeKalb County Public Works Department have devoted a large amount of resources that have not been paid for by DOE. It is highly probable that cost recovery will be pursued at a later date by one or more of the participants, once liability for the incident has been fixed.

The question of whether cost recovery is an issue that should be considered in licensing irradiator facilities is under study by the Conference of Radiation Control Program Directors, Inc. and the results are not available at this time.

1.5.5.6 Community Relations

During the time of the RSI incident, there was a great deal of concern about the situation from nearby business neighbors as well as the general public in the area. Because of this concern, the State of Georgia developed a Community Relations Plan rather rapidly and implemented it during the first few days of the incident. Not only did RSI not have such a plan, the company was not prepared to relate to the public's concerns. In fact, until the incident occurred, the surrounding neighbors in the Snapfinger Woods Business Park did not know that RSI-Decatur was a commercial irradiator facility.

There is a definite need for a Community Relations Plan. There are a number of mechanisms for causing such a plan to be created by the irradiator facility. One such mechanism that should be evaluated is the requirement in the license for a Contingency Plan with the inclusion of a Community Relations Plan that can be activated by the company when the need arises.

1.5.5.7 Requirement for Early Warning Process

The RSI incident has already demonstrated that more attention must be focused on a number of areas to improve the regulatory process for commercial irradiators. In order to allow more time for regulatory authorities to become familiar with the proposed activities of irradiators, an "early warning process" should be considered prior to the submittal of a completed license application for a facility. In addition, minimum time and check points may need to be built into the license review process to negate pressure on regulatory authorities to issue the license in an expedited manner.

1.5.5.8 Future Role of Agreement States in Licensing Commercial Irradiators

Because of the potential for expansion of the number of irradiator facilities in the United States, particularly if the food sterilization market materializes, the question arises as to whether the Agreement States' resources will be sufficient to license, conduct the necessary compliance monitoring, and manage a recovery incident such as that which occurred at RSI-Decatur. This is a very viable issue and is one best evaluated by the Conference of Radiation Control Program Directors, Inc. (CRCPD). While the CRCPD study is currently ongoing and preliminary results are not yet available,* no information has been uncovered to suggest Agreement States cannot effectively regulate commercial irradiators. The findings of the CRCPD will be included in a Final Report of the RSI Incident Evaluation Task Force.

1.5.5.9 Future Use of WESF Capsules

The DOE Investigative Board has not completed its investigation of the RSI incident and the relationship of WESF Capsule integrity to the incident. However, it is obvious that capsule integrity is an issue and that the information supporting the decision to use the WESF capsules in commercial irradiators is surrounded by serious controversy. The RSI incident has not only generated world-wide concern, but also resulted in the use of a large number of

*An interim report was prepared by a CRCPD Incident Review Team subsequent to this State report and is found in Appendix C, page 32.

taxpayers' dollars to date in just identifying and removing the two damaged WESF capsules. Not only have significant questions been raised about WESF capsule integrity at the two licensed irradiator facilities that are still in operation, but an even larger question exists as to whether WESF capsules should ever be used again or continued to be allowed to be used in commercial irradiators because of cesium-137 chloride is highly soluble in water. The International Atomic Energy Agency in its report, "The Radiological Accident in Goiania" (which involves a large Cs-137 chloride source that was ruptured), commented: "the physical and chemical properties of radioactive sources are very important in relation to radiological accidents. They should be taken into account in the licensing for manufacture of such sources, in view of the potential influence of these properties on the consequences of accidents with the use or misuse of sources." This is not an issue to be taken lightly by DOE or NRC. This issue needs to be fully resolved to the satisfaction of all cognizant regulatory agencies involved.

APPENDIX A

CHRONOLOGICAL HISTORY OF RSI INCIDENT
(THRU 1-31-89)

DATE	EVENT
3-19-84	RSI submitted an application to State of Georgia, Department of Human Resources (DHR), for a radioactive materials license to use either cobalt-60 or cesium-137 for sterilization in a Category IV Gamma Irradiator.
12-7-84	DHR issued a license to RSI for possession and storage of only cobalt-60 at its Decatur, Georgia facility.
2-2-85	DHR amended the RSI license to allow the use of cobalt-60 for sterilization purposes.
10-21-85	The U.S. Nuclear Regulatory Commission (NRC) notified the U.S. Department of Energy (DOE) and the Agreement States that it would consider other license applications for use of Cs-137 WESF sources in irradiators of the "wet load, wet storage, dry irradiation" mode of operation.
1-6-86	The State of Georgia (DHR) amended the RSI radioactive materials license for its Decatur facility to authorize the possession and use of 12.3 megacuries of cesium-137.
6-6-88	° The safety system at the RSI-Decatur facility indicated a problem at the cell about 0800. RSI personnel entered the cell area and measured radiation levels of 60 millirem per hour at the surface of the pool water.
	° RSI notified the Georgia DHR of the incident and began initial surveys of operating personnel.
	° Preliminary surveys of product, still remaining in the cell from June 4 and June 5, showed spots of radioactive contamination.
	° RSI began telephone c lls to distributors warehouses and requested that they hold all sterilized products received from the RSI-Decatur facility until further notice.

DATE	EVENT
	° Site visit to RSI-Deα tur facility by Georgia DHR personnel.
6-7-88	° DHR issued a license amendment to RSI to stop any further product irradiation at its Decatur facility because of a leaking source.
	° A shipment that had left RSI at 0800 on 6-6-88, en route to Jacksonville, Florida., was returned to RSI-Decatur. Later monitoring showed contaminated surfaces on the outside of several packages.
	° The Georgia DHR formally notified the U.S. Nuclear Regulatory Commission's Region II office in Atlanta of the RSI-Decatur situation.
	° U.S. NRC issued a PN (preliminary notification) about the RSI incident.
	° Health physics personnel from Westinghouse Hanford Corp. (a U.S. DOE contractor) arrived at RSI-Decatur.
	° In-house monitoring of various areas within the RSI-Decatur building revealed the presence of radioactive contamination.
6-8-88	Georgia DHR secured the services of a professional consultant, Dr. Melvin Carter, to assist with evaluation of the RSI incident.
6-9-88	° Environmental surveys outside the RSI-Deα tur building were conducted by a joint NRC/Georgia Department of Natural Resources (DNR) team about 0100. No contamination was detected.
	° Internal meetings which involved senior management officials of the State of Georgia resulted in the designation of the Georgia DNR as the lead State agency to manage the RSI incident.
	° An initial management plan was jointly developed by DNR with NRC and DHR. RSI was then advised as to how the incident would be handled.
	° DHR and RSI continued the survey of RSI employees, their homes, and their automobiles.

DATE		EVENT
	°	NRC began coordination of a national effort to survey the undistributed products that had been sterilized during the period April 29, 1988 - June 5, 1988. April 29 was the last "clean date of record," determined from pool water analysis.
6-10-88	°	The Georgia DNR moved a command post and mobile laboratory to the RSI-Decatur site.
	°	DHR, assisted by NRC, continued monitoring of RSI personnel.
6-11-88		The State of Georgia (DNR) formally requested that the U.S. Department of Energy, who owns the cesium-137 capsules leased to RSI, manage the identification of leaking cesium-137 (Cs-137) capsules at the RSI facility, the subsequent removal of damaged sources, and the recovery activities. DOE agreed and named a site manager.
6-15-88		Product surveys at distribution centers completed.
6-21-88		DOE Source Identification Task Plan completed.
6-28-88		Westinghouse Hanford Corporation (WHC) began in-rack visual examination of source capsules at RSI-Decatur.
7-7-88		WHC began out-of-rack examination of source capsules.
7-16-88		Initial capsule screening completed. Twenty-nine out of 252 capsules identified as "suspects" on basis of visual anomalies, of which two showed positive ultrasonic test results.
7-17-88 to 8-1-88		Reexamination of "suspect capsules."
8-1-88		DOE began design and fabrication of an in-situ leaking source detection system at Oak Ridge Operations.
8-17-88	°	In-situ leaking source detection system delivered to the RSI-Decatur site.
	°	Capsule No. 1134 removed and shipped to Oak Ridge operations for nondestructive testing.

DATE	EVENT
8-24-88	Preliminary results of the non-destructive testing of Capsule No. 1134 completed by DOE. Results showed it was not leaking.
8-18-88 to 9-15-88	In-situ testing of RSI "suspect" capsules.
9-16-88	The two capsules (1507 and 1542) that showed positive ultrasonic test results were removed and shipped to Oak Ridge Operations for evaluation.
10-7-88 to 10-12-88	Increase of Cs-137 release rate into the RSI pool to over 600 microcuries per hour. (Previous rate of 25 microcuries per hour.)
10-15-88	DOE testing of Capsules 1507 and 1542 completed. Neither of the two was a leaker.
11-3-88	Arrival of a special fabricated "six pack sipper" at RSI-Decatur for detailed in-situ evaluation.
11-13-88	Actual evaluation with use of the "six pack sipper" began.
11-20-88	Identification of Capsule No. 1502 as being bulged and would not fit into the sipper.
11-21-88	Preliminary confirmation through isolation that 1502 was a leaker.
12-03-88	Identification of a second bulged capsule (No. 1504).
12-20-88	Packaging and shipment of Capsules Nos. 1502 and 1504 to Oak Ridge Operations for evaluation.
1-17-89	DOE released an interim report, "Examination of Capsules 1502 and 1504." Capsule 1502 is a confirmed leaker and Capsule 1504 is not leaking.
1-31-89	In-pool monitoring at RSI-Decatur by DOE and DNR shows that radiation levels have dropped to 10^{-6} microcuries per milliliter and have remained reasonably constant, thus indicating a very low probability of another leaking capsule.

APPENDIX B

TASK FORCE MEMBERS

Mr. Paul Burks, Director
Office of Energy Resources
270 Washington Street, S.W.
Suite 615
Atlanta, Georgia 30334

Mr. William E. Cline, Chief
Nuclear Materials Safety and
Safeguards Branch
U.S. Nuclear Regulatory Commission
101 Marietta Street, N.W.
Atlanta, Georgia 30318

Thomas Hill, Acting Director
Radiological Health Services
Georgia Department of Human Resources
878 Peachtree Street, N.E.
Atlanta, Georgia 30309

Mr. Joel Lubenau, Senior Project Manager
State Programs
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852

Mr. James L. Setser, Chief
Program Coordination Branch
Environmental Protection Division
Georgia Department of Natural Resources
205 Butler Street, S.E., 1152 East Tower
Atlanta, Georgia 30334

Mr. Richard Woodruff
Regional State Agreements Officer
U.S. Nuclear Regulatory Commission
101 Marietta Street, N.W.
Atlanta, Georgia 30318

APPENDIX C

INTERIM REPORT

The Licensing and Regulation of Irradiator Facilities by Agreement States

Prepared by the Conference of Radiation Control Program Directors, Inc.
Incident Review Team

Greta J. Dicus, Arkansas
David K. Lacker, Texas
Thomas M. Gerusky, Pennsylvania
September 1989

INTERIM REPORT - THE LICENSING AND REGULATION OF IRRADIATOR FACILITIES BY AGREEMENT STATES

1. Introduction

The Incident Review Team (the Team) was originally established by the Conference of Radiation Control Program Directors, Inc. (CRCPD) to provide a lessons learned report on the Radiation Sterilizers, Inc. (RSI) incident near Atlanta, Georgia. Following the establishment of the Georgia RSI Incident Task Force (the Task Force), by Georgia Governor Joe Frank Harris, the Team assumed the responsibility of addressing one of the objectives identified by the Task Force. That objective is "prepare a discussion of the role of the States in regulating facilities such as RSI to include the development of regulatory standards, licensing and regulating facilities, and responding to incident."

In order to address the issues relative to this objective, a questionnaire was developed and sent to all Agreement States as well as those States considering Agreement State status.

This interim report contains a summary of the responses, recommendations based upon the responses, and a discussion of the responses to each question.

2. Summary

° The licensing of an irradiator is generally considered to be a more complex task relative to most licensing actions. Therefore, the licensing agency will usually have to address special licensing issues and/or specific problems.

° All States having irradiators are confident of their ability to license and regulate these facilities. Most States not having an irradiator either are not confident of their resources or are uncertain they have adequate resources.

° The regulation of irradiators should not be the exclusive jurisdiction of the U.S. Nuclear Regulatory Commission (NRC).

° Regarding irradiator regulations:

(1) Only a few of the States have specific regulations for irradiators.

(2) Slightly less than half of the States believe the proposed NRC regulations are adequate. However, most of the remaining States were either uncertain through lack of experience with irradiators or had no comment. A few States believed the proposed regulations are inadequate.

(3) Most States do not believe there should be special regulations for food irradiators.

° There is disagreement among the States on the adequacy of guidance documents on irradiator standards for licensing and regulation.

° There should be advance notification of the intent of a company to construct an irradiator facility.

° Construction standards for irradiators should be developed.

° The WESF capsules should not be used in wet source storage irradiators.

3. Recommendations

° A guidance document should be developed by CRCPD, Inc. which, in addition to addressing licensure and regulation, should also address construction standards and provide an index of other irradiator documents concerning component standards. Development of the guidance document could be part of the work of a task force or committee charged with development of other guidance documents.

° With State input, the NRC should continue action on proposed regulations for irradiators, but these should not be a matter of compatibility. Suggested State regulations should then be developed by CRCPD, Inc. Regulations should address the issues raised by the States and lessons learned from the RSI task force report.

° Sources used in irradiators must be manufactured specifically for that purpose and must be properly tested and used only in the type irradiator for which they were designed.

4. Discussion

Questionnaires were sent to 32 States, 21 of which responded. Of the responders, 11 have irradiators and 10 do not.

Of States with irradiators, 83% identified special licensing considerations. They were:

° worker protection
° source leakage and detection
° public relations concerns
° notification requirements for source loading
° local hospital agreements
° formal training program
° siting requirements
° notification of incidents

° quality assurance
° prenotification of intent to construct
° prelicensing inspections
° seismic evaluation
° bonding/financial security
° cell security.

Those States with irradiators expressed confidence in their regulatory capabilities. The most prevalent reason given (by over half the States) was that their radioactive material licensing staffs have enough experience in licensing that they are able to handle the more complex applications. Another reason stated by several States was confidence that they could get technical assistance from federal agencies or other States. Other reasons listed were:

° more than one agency would be involved in the process
° have the appropriate equipment
° have emergency response capability
° have legal assistance.

Several of the States expressing concern about their capabilities indicated the need for additional staff and/or additional training for current staff. Limited budgets and instrumentation for independent measurements were also cited by these States. Another concern was the ability to respond to incidents.

All 21 responders stated that the States should retain regulatory jurisdiction over irradiators including those that questioned their own capability to do so. (We conclude that in the later case there is a confidence that given adequate notification of the intent to construct a facility, these States can acquire the needed resources in a timely fashion to license and regulate the facility.) The reason most frequently given in support of State jurisdiction was that the State agency could do an equal or better job than the NRC presumably because of technical capabilities and being close to the facility allowing closer oversight.

Two of the responding States have specific regulations for irradiators. Other States with irradiators use existing regulations for general radiation safety concerns and addressed the specific issues by license condition.

Regarding the proposed NRC regulations*, three States indicated that the regulations are inadequate and suggested the following changes.

° Inspections be conducted by consultants with reports sent to the regulatory agency(ies).

° Siting should be addressed.

° Delete the proposed regulation that allows irradiator operation without an authorized user on site.

° Fire protection/detection devices should be required.

Nine States believed the proposed NRC regulations are adequate and nine States either had not reviewed them or could not evaluate them because personnel had no experience with irradiators.

Regarding specific regulations/requirements for food irradiators, fifteen States said such regulations should not be written. The two reasons cited by most States were:

(1) The product irradiated should not drive the regulations.

(2) There are FDA requirements which address the handling of food products.

Other reasons cited were:

(1) Leakage and product contamination are the only areas of special concern and can be handled without special regulations.

(2) Use license conditions for special applications.

Three States suggested regulations should be written specifically for food irradiation. These States considered food irradiation to be a specialized process with the potential for serious

*Each of the Agreements with the 29 Agreement States provide for NRC and the Agreement State to "use its best efforts to cooperate...in the formulation of standards and regulatory programs...and to keep each other informed of proposed changes in their respective rules and regulations...and to obtain the comments and assistance of the other party thereon." Under this provision, NRC staff sought Agreement State comments and input to the development of proposed rules for irradiators. As of the publication date of this NUREG report, the proposed rulemaking has not been approved for publication by NRC in the Federal Register for public comment.

ramifications in the event of an incident thus indicating the need for special regulations. Specific details of what should be included in the regulations other than FDA requirements and contamination control were not addressed.

Three States had no opinion.

There is considerable lack of consensus regarding the adequacy of guidance for irradiator standards and licensing suggesting that there is a need for greater effort in this area. Six States believe the guidance is adequate and cite the existence of NUREG documents (although they were not specific) review plans, ANSI standards and at least one State has developed its own standards. Additionally, there has been at least one major workshop conducted by the NRC.

However, eight States strongly believed the guidance to be inadequate listing concerns over the lack of bonding and surety requirements and the fact that current guidance lacks sufficient detail such as thermal considerations. Several States suggested the need for a regulatory guide on irradiator facility construction.

Seven States had no opinion or were uncertain about the adequacy of the guidance. Almost all of these States had not reviewed what is available because they do not have irradiators.

Regulatory authorities want advance notice of the intent of a potential licensee to construct an irradiator. Interest was so strong on this issue that advance notice should be a regulatory requirement. The States were also in close agreement on why advance notice is preferred with most States citing the following reasons:

° Prenotification allows for the establishment of siting criteria and planning standards and allows for prelicensing visits.

° Regulatory agencies can better prepare to regulate these facilities (especially important if the program has not previously licensed a facility) and can address potential problems for better compliance and oversight, now and in the future.

Regarding standards for construction of irradiators, the following list was generated from responses:

° Siting criteria

1. topography and geology
2. location including proximity to populated/residential areas
3. earthquake potential
4. hydrogeology

° Quality Assurance and Standards

1. ANSI standards
2. construction and component part material's ability to withstand high radiation levels
3. source testing
4. component parts testing

° Design Criteria

1. general mechanical design
2. shielding
3. source racks
4. corrosion prevention
5. ventilation
6. pool
7. fire detection/protection/prevention

° Radiation Safety Systems

1. access control
2. source detection
3. radiation levels
4. leak testing

° Emergency Procedures

1. power failures
2. backup water
3. contamination control
4. fail safe systems

Regarding the WESF capsules, eight States not familiar with them offered no opinion regarding their use in commercial irradiators. States familiar with the capsules indicated that they should not have been used as they were, many States expressed concern over how this issue was handled by the federal agencies involved.