SEC Petition Evaluation Report
Petition SEC-00033

Report Rev # 0 Report Submittal Date 7-20-2006

Subject Expert(s):	LaVon B. Rutherford
Site Expert(s):	
Independent Technical Reviewer:	

Petition Administrative Summary

Petition Under Evaluation

Petition #	Petition Type	Qualification Date	DOE/AWE Facility Name
SEC-00033	83.13	October 6, 2005	Oak Ridge Institute of Nuclear Studies (ORINS)

Feasible to Estimate Doses with Sufficient Accuracy?

Single Class				Multiple Classes				Determination Established for All Classes			
Yes		No	X	Yes		No		Yes	X	No	

Initial Class Definition

All Medical Division employees that worked at the Oak Ridge Institute of Nuclear Studies from June 1, 1950 through June 25, 1956.

Proposed Class Definition

Employees of the DOE or DOE contractors or subcontractors who were monitored, or should have been monitored, while working at the Oak Ridge Institute of Nuclear Studies Cancer Research Hospital from May 15, 1950, through December 31, 1963, and who were employed for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days within the parameters (excluding aggregate work day parameters) established for other classes of employees included in the SEC.

Related Petition Summary Information

SEC Petition Tracking #(s)	Petition Type	DOE/AWE Facility Name	Petition Status
NONE			

Related Evaluation Report Information

Report Title	DOE/AWE Facility Name
NONE	

Lead Technical Evaluator:	**Signature on file** *LaVon B. Rutherford*	7/20/2006 *Date*
Peer Review Completed By:	**Signature on file** *James W. Neton*	7/20/2006 *Date*
SEC Petition Evaluation Approved By:	**Signature on file** *Larry Elliott*	7/20/2006 *Date*

This page intentionally blank

Evaluation Report Summary: SEC-00033, ORINS

This evaluation report by the National Institute for Occupational Safety and Health (NIOSH) addresses a class of employees proposed for addition to the Special Exposure Cohort (SEC) per the *Energy Employees Occupational Illness Compensation Program Act of 2000*, as amended, 42 USC (EEOICPA) and 42 CFR 83, *Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000*.

Petitioner Requested Class Definition

Petition SEC-00033, qualified on October 6, 2005, requested NIOSH to consider the following class: *All Medical Division employees that worked at the Oak Ridge Institute of Nuclear Studies from June 1, 1950 through June 25, 1956.*

NIOSH Proposed Class Definition

This evaluation defines a single class of employees for which NIOSH cannot estimate radiation doses with sufficient accuracy. This class includes: *Employees of the DOE or DOE contractors or subcontractors who were monitored, or should have been monitored, while working at the Oak Ridge Institute of Nuclear Studies Cancer Research Hospital from May 15, 1950, through December 31, 1963, and who were employed for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days within the parameters (excluding aggregate work day parameters) established for other classes of employees included in the SEC.*

Feasibility of Dose Reconstruction

Per EEOICPA and 42 CFR § 83.13(c)(1), NIOSH has established that it does not have access to sufficient information to: (1) estimate either the maximum radiation dose incurred by any member of the class; or (2) estimate such radiation doses more precisely than a maximum dose estimate. The sum of information from the available resources is not sufficient to document or estimate the potential maximum internal exposure to members of the class under plausible circumstances during the period from May 15, 1950, through December 31, 1963.

Health Endangerment

Per EEOICPA and 42 CFR § 83.13(c)(3), NIOSH did not identify any evidence from the petitioners or from other resources that would establish that the class was exposed to radiation during a discrete incident likely to have involved exceptionally high level exposures. However, the evidence reviewed in this evaluation indicates that some workers in the class may have accumulated substantial chronic exposures from the inhalation and ingestion of radionuclides, combined with external exposures to gamma and beta radiation. Consequently, NIOSH has determined that health was endangered for those workers covered by this evaluation who were employed for a number of work days aggregating at least 250 work days within the parameters established for this class or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

This page intentionally blank

Table of Contents

Tables

SEC Petition Evaluation Report for SEC-00033

1.0 Purpose and Scope

This report evaluates the feasibility of reconstructing doses for Oak Ridge Institute of Nuclear Studies (ORINS) employees at the ORINS Cancer Research Hospital in Oak Ridge, Tennessee, during the period from May 15, 1950, through December 31, 1963. It provides information and analyses germane to considering a petition for adding a class of employees to the congressionally-created SEC.

This report does not provide any determinations concerning the feasibility of dose reconstruction that necessarily apply to any individual energy employee who might require a dose reconstruction from NIOSH. This report does not make the final determination as to whether or not the proposed class will be added to the SEC (see Section 2.0).

This evaluation was conducted in accordance with the requirements of EEOICPA, 42 CFR 83, and the guidance contained in the Office of Compensation Analysis and Support's *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions,* OCAS-PR-004.

2.0 Introduction

The EEOICPA and 42 CFR 83 require NIOSH to evaluate qualified petitions requesting the Department of Health and Human Services (HHS) to add a class of employees to the SEC. The evaluation is intended to provide a fair, science-based determination of whether or not it is feasible to estimate with sufficient accuracy the radiation doses of the class of employees through NIOSH dose reconstructions.[1]

42 CFR § 83.13(c)(1) states: *Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose.*

Under 42 CFR § 83.13(c)(3), if it is not feasible to estimate with sufficient accuracy radiation doses for members of the class, NIOSH must also make a determination whether or not there is a reasonable likelihood that such radiation doses may have endangered the health of members of the class. The regulation requires NIOSH to assume that any duration of unprotected exposure may have endangered the health of members of a class when it has been established that the class may have been exposed to radiation during a discrete incident likely to have involved levels of exposure similarly high to those occurring during nuclear criticality incidents. If the occurrence of such an exceptionally high level

[1] NIOSH dose reconstructions under EEOICPA are performed using the methods promulgated under 42 C.F.R. pt. 82 and the detailed implementation guidelines available at www.cdc.gov/niosh/ocas.

exposure has not been established, then NIOSH is required to specify that health was endangered for those workers who were employed for at least 250 aggregated work days either solely under the employment or in combination with work days within the parameters established for other SEC classes (excluding aggregate work day requirements).

NIOSH is required to document the evaluation in a report. For development of the evaluation report, NIOSH relies on its own dose reconstruction expertise, and typically, on technical support from Oak Ridge Associated Universities (ORAU). However, in this case, ORAU (formerly ORINS) has a conflict of interest issue and did not participate in this evaluation. Upon completion, the report is provided to the petitioners, the Advisory Board on Radiation and Worker Health, and the public. The Board will consider the NIOSH evaluation report, together with the petition, petitioner(s) comments, and other information the Board considers appropriate, to make recommendations to the Secretary of HHS on whether or not to add one or more classes of employees to the SEC. Once NIOSH has received and considered the advice of the Board, the Director of NIOSH will propose decisions on behalf of HHS. The Secretary of HHS will make final decisions, taking into account the NIOSH evaluation, the advice of the Board, and the proposed decisions and recommendations of the Director of NIOSH. Following this decision process, petitioners may seek a review of certain types of final decisions issued by the Secretary of HHS.[2]

3.0 Petitioner Requested Class/Basis and Class(es) Evaluated by NIOSH

Petition SEC-00033, as qualified on October 6, 2005, requested HHS to consider the addition to the SEC a class of all Medical Division employees at the ORINS from June 1, 1950, through June 25, 1956. The petitioner asserted by affidavit that energy employees who meet the proposed class definition did not receive monitoring for potential internal radiation exposures. Records available to NIOSH support the petitioner's statement that all such employees were not routinely monitored for internal exposures through bioassay or other in vivo means. NIOSH also concluded it was reasonable to assume that there was a potential for internal exposure based on the processes involved in preparing, administering, and disposing of radioactive materials for cancer research and treatment. Accordingly, the evidence provided by the petitioner qualified the petition for further consideration by NIOSH, the Board, and HHS.

NIOSH modified the time period of the petitioner-requested class, for the purposes of this evaluation, to May 15, 1950, to December 31, 1963, because: (1) the first cancer patient was admitted to the facility on May 15, 1950; and (2) internal exposure monitoring records are not available for any years of operation up until 1964.

[2] See 42 C.F.R. pt. 83 for a full description of the procedures summarized here. Additional internal procedures are available at www.cdc.gov/niosh/ocas.

4.0 Data Sources Reviewed by NIOSH

NIOSH identified and reviewed many data resources to determine the availability of information relevant to determining the feasibility of dose reconstruction for the class of employees covered by the petition. This included determining the availability of information on personal monitoring, area monitoring, hospital processes, and radiation source materials. The following sections summarize the resources identified and reviewed.

4.1 Site Profile Technical Basis Documents (TBDs)

NIOSH has not prepared a Site Profile to cover the ORINS Cancer Research Hospital.

4.2 ORAU Technical Information Bulletins (OTIBs)

An ORAU Technical Information Bulletin (OTIB) is a general working document that provides guidance concerning the preparation of dose reconstructions and particular sites or categories of sites. NIOSH reviewed the existing OTIBs describing the methods for dose reconstruction to consider their usefulness for reconstructing doses for members of the proposed SEC class. The following TIB was identified as having relevance to dose reconstructions for members of the class:

- *OTIB: Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*; ORAUT-OTIB-0006, Rev. 3, PC1; December 21, 2005

4.3 Facility Employees and Experts

NIOSH interviewed five workers who were employed at ORINS during the proposed class period or very close to the proposed class period. The workers consisted of two research scientists, two health physicists, and a nurse. Two of the workers are existing EEOICPA claimants. Although the claimants were interviewed as part of their dose reconstruction, they were interviewed again to address additional questions about the facility and potential exposures.

4.4 Previous Dose Reconstructions

NIOSH reviewed its dose reconstruction database, NIOSH OCAS Claims Tracking System (NOCTS), to identify dose reconstruction cases under EEOICPA that might provide information relevant to the petition evaluation. Table 4-1 provides a results summary of this review for the May 15, 1950, through December 31, 1963, time frame.

Table 4-1: No. of ORINS Claims Submitted Under the Dose Reconstruction Rule (May 15, 1950, through December 31, 1963)	
Description	**Totals**
Number of cases submitted for energy employees who meet the proposed class definition employment period criteria.	11
Number of dose reconstructions completed for energy employees who were employed by ORINS at the ORINS Cancer Research Hospital during the years identified in the proposed class definition.	5
Number of cases for which internal dosimetry records were obtained for ORINS employees at the ORINS Cancer Research Hospital for the identified years in the proposed class definition.	0
Number of cases for ORINS employees at the ORINS Cancer Research Hospital for which external dosimetry records were obtained for the identified years in the proposed class definition.	8

NIOSH reviewed each claim to determine whether internal and/or external personal monitoring records could be obtained for the employee. As indicated in Table 4-1, NIOSH has been able to obtain external monitoring records for the 11 cases that meet the class definition. No internal monitoring data were available from the claimants' Department of Energy files. NIOSH also reviewed the interviews conducted with claimants for these cases to determine whether they had provided relevant information for dose reconstruction. The interviews provided some information that would be useful for dose reconstructions (i.e., work locations, hours worked, and hazards encountered) and identified conditions for which there would have been a potential for internal exposures.

4.5 NIOSH Site Research Database

The NIOSH site research database (SRDB) was reviewed for documents to support the evaluation of the proposed class. The database contained some useful information on external exposure rates, radiological controls, medical procedures using radiation-generating devices and radioisotopes injections, and other ORINS historical information.

4.6 PubMed Database

Radiological activities conducted at the ORINS Cancer Research Hospital were not typical of the weapons complex. The facility conducted research in nuclear medicine, particularly for the treatment of cancer. Therefore, NIOSH also searched nuclear medicine research literature for evaluations of occupational exposure hazards in nuclear medicine.

NIOSH searched the PubMed database, a service of the U.S. National Library of Medicine, to identify reports on potential occupational exposures to medical personnel while preparing, administering, and disposing of radioisotopes administered for medical purposes. NIOSH obtained 13 relevant documents (See References: AMA-1951; MED-1950; Rad-1980; HP-1985; HP-2005; Chem-1980;

HP-1999; NucMed-Jun2003; NucMed-May2003; Thyroid-1997; NucTech-2002; and HP-1962). These included a report providing ORINS-specific information concerning radioisotope hazards in medical applications. This report (AMA-1951) titled, *Radioisotope Hazards and Protection in a Hospital*, was authored by Dr. Marshall Brucer, head of the Medical Division of ORINS during the period covered by this evaluation.

4.7 Documentation and/or Affidavits Provided by the Petitioners

In qualifying and evaluating the petition, NIOSH reviewed the following documents submitted by the petitioners:

- Petition Form B and supporting information provided with the petition; SECIS multi-document ID: 8830, received May 5, 2005.

- ORINS historical information for 1950 though 1956; ORAU History section of the Oak Ridge Associated Universities (formerly ORINS) website (www.orau.org); SECIS multi-document ID: 8830, received May 5, 2005.

- Overview of ORINS nuclear medicine instrumentation (with photos); ORAU History section of the Oak Ridge Associated Universities (formerly ORINS) website (www.orau.org); SECIS multi-document ID: 8830, received May 5, 2005.

- Provenance Form for Medical Sciences Division Human Radiation Experiments; SECIS multi-document ID: 8830, received May 5, 2005.

- *Information for Patients*, brochure from the ORINS Medical Division; SECIS multi-document ID: 8830, received May 5, 2005.

- List of isotopes used by the Medical Division; SECIS multi-document ID: 8830, received May 5, 2005.

- Excerpts from book review of *Plutonium Files* by Eileen Welsome; SECIS multi-document ID: 8830, received May 5, 2005.

- Excerpts from the ACHRE Report; Atomic Energy Commission; SECIS multi-document ID: 8830, received May 5, 2005.

- Excerpts from *Human Radiation Studies: Remembering the Early Years*: Oral History of Oncologist Helen Vodopick, M.D.; SECIS multi-document ID: 8830, received May 5, 2005.

- Notarized petitioner-proposed SEC class definition; SCE document ID: 9201; received August 26, 2005.

5.0 Radiological Operations Relevant to the Proposed Class

The following subsections summarize the radiological operations at the ORINS from May 15, 1950, through December 31, 1963, and the information available to NIOSH to characterize particular processes and radioactive source materials. From available sources, NIOSH has gathered the available process and source descriptions, information regarding the identity and quantities of each radionuclide of concern, information describing the process through which the radiation exposures of concern may have occurred, and information regarding the physical environment in which radiation exposures may have occurred.

5.1 ORINS Cancer Treatments and Process Descriptions

In January, 1949, the ORINS organized a Medical Division with the primary function of exploring the use of radioisotopes in the field of medicine (AMA-1951). Construction of the ORINS Cancer Research Hospital began on June 25, 1949. The 30-bed hospital and laboratory were completed in 1950. The first patient was accepted for treatment on May 15, 1950 (ORAU 1949).

The first patients accepted by the division were those afflicted with diseases for which the therapeutic use of radioisotopes was already generally established. The major focus of the Medical Division at that time was investigating new types of isotope treatment (ORAU 1949).

During the early 1950s, ORINS Medical Division used a variety of cancer treatment methods involving the administration of various radioisotopes. Using the available ORINS annual reports from 1952-1964 (ORINS-1952 – ORINS-1964), NIOSH has developed a timeline listing the activities conducted by the Medical Division for those years (Table 5-1).

Table 5-1: ORINS Medical Division Activities Timeline

Year	Activities
1950	• Radioiodine Treatment for thyroid cancer Note: NIOSH probably lacks complete information to identify activities for this year.
1951	• Radioiodine Treatment for thyroid cancer Note: NIOSH probably lacks complete information to identify activities for this year.
1952	• Radioiodine treatment for thyroid cancer • Cobalt-60 Teletherapy unit (200-curie source) • Gallium-67 and -72 ingestion for treatment of bone cancer • Administration of Gold-198 for palliation of advanced neoplasms
1953	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • 800-curie cobalt-60 Irradiator (modified from 200-curie to 800-curie in July, 1952)
1954	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • A 300-600 curie cobalt-60 Teletherapy unit and a kilo-curie cesium-137 moving beam unit were used for external delivery of radiation.

Table 5-1: ORINS Medical Division Activities Timeline	
Year	**Activities**
1955	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • A 300-600 curie cobalt-60 Teletherapy unit and a kilo-curie cesium-137 moving beam unit were used for external delivery of radiation. • Thyroid uptake calibration program using barium-133 and cesium-137
1956	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • A 300-600 curie cobalt-60 Teletherapy unit and a kilo-curie cesium-137 moving beam unit were used for external delivery of radiation. • Thyroid uptake calibration program continued using barium-133 and cesium-137 • Portable strontium-barium X-ray source
1957	• Same as 1956
1958	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • A 300-600 curie cobalt-60 Teletherapy unit and a kilo-curie cesium-137 moving beam unit were used for external delivery of radiation. • Thyroid uptake calibration program continued using barium-133 and cesium-137 • Portable strontium-barium X-ray source • A leak occurred in the cobalt-60 Teletherapy unit. • The Medical Division began designing a whole body counter. • Medical Division evaluated the use of a radium source for treatment of carcinoma of the cervix.
1959	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • Thyroid uptake calibration program continued using barium-133 and cesium-137 • The Medical Division continued designing a whole body counter. • The total body irradiator was constructed and installed. The unit contained 8 – 500 curie cesium sources.
1960	• A number of isotopes were administered internally, including: phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-131, and gallium-67. • Thyroid uptake calibration program continued using barium-133 and cesium-137 • The Medical Division continued designing a whole body counter. The Division narrowed down to two types of detectors: a sodium iodide crystal and a “tank” detector system. • The total body irradiation facility was released for clinical operation in May, 1960.
1961	• No annual report available. However, based on other documents it is reasonable to assume that all work occurring in 1960 continued in 1961.
1962	• Teletherapy work continued with the cesium and cobalt sources. • The Medical Division continued work on a whole body counter. • A number of isotopes were administered internally, including: barium-133, chromium-51, phosphorous-32, gold-198, yttrium-90, leutecium-177, iodine-125, -130, and -131, and iron-58 and -59.
1963	• No annual report available. However, based on other documents it is reasonable to assume that all work occurring in 1962 continued in 1963.
1964	• The Medical Division began its whole body counting program.

5.2 Radiological Exposure Sources

ORINS recognized at the time that the potential for external occupational radiation exposures was most substantial, as evidenced by the radiological safety program instituted. Although there was also potential for substantial internal exposures arising from preparing, administering, and disposing of radioisotopes and radioactive waste, NIOSH found no evidence of personnel or workplace monitoring that could be used to bound internal radiation exposures The following sections summarize these external and internal exposure circumstances.

5.2.1 External Exposures

External exposures to Medical Division personnel were well documented. External exposures occurred through a variety of processes and circumstances associated with the use of radioactive medicines administered internally to patients, and with the radiation-generating devices used to provide treatments using an external radiation source. A good example of the actual external exposures received by various working classes of ORINS personnel is documented in the report, *Radioisotope Hazards and Protection in a Hospital* (AMA-1951). In that report, the ORINS Medical Division studies exposures to personnel over a three-month period. During the period, there was an average hospital load of 17 patients undergoing some type of radiation therapy. The isotopes brought in during that period were 3.98 curies of Ga^{72}; 2.12 curies of Au^{198}; 1.11 curies of I^{131}; .04 curies of P^{32}; 0.02 curies Na^{24}. Table 5-2 was recreated from a table in that report.

Table 5-2: Exposure of Selected Personnel Measured by Routine Film Badges Over a 3-Month Period (Dec. 1950 through Feb. 1951)

Type of Work	No. with Blank Badge	No. Exposed	Avg. mr/day Exposure		Largest Avg. Exposure in Group (mr/day)
			Open Window	Closed Window	
Staff (M.D. or Ph.D)	3	10	9.1	9.1	55.7
Part-time Staff	1	3	2.0	3.9	10.9
Technicians	2	9	10.3	11.9	28.5
Nurses	0	12	4.9	3.9	10.6
Nurse aids	0	6	4.1	3.7	5.9
Orderlies	0	2	12.2	11.4	15.9
Maids	0	2	1.8	1.8	3.1
Maintenance Men	4	3	0.6	0.6	0.6
Administrative	1	4	1.5	1.3	4.2
Total Personnel	11	51	6.1	6.1	55.7

As can be seen in Table 5-2, the highest average daily exposures were received by: the technicians who handled the urine, feces, blood, and tissue samples; the doctors and staff chemists who administered the radioactive medicines and prepared the medicines; and the orderlies who spent most of their time caring for the needs of the patients (AMA-1951). However, it is important to note that even the administrative staff received some daily exposures.

Another table presented in this report identifies external exposures to the surgeon, first assistant, and another assistant or anesthetist during five different surgical operations. This data is presented in Table 5-3 below:

Table 5-3: Exposure to Radioactivity during Surgical Operations (mr Total Exposure: Hands and Body) (Dec. 1950 through Feb. 1951)

Operation	Surgeon			First Assistant			Assistant/Anesthetist		
	Left Hand	Right Hand	Total Body	Left Hand	Right Hand	Total Body	Left Hand	Right Hand	Total Body
Laparotomy	Neg.	Neg.	10	Neg.	Neg.	10	…	…	10
Laparotomy	155	75	40	35	35	10	50	…	10
Laparotomy	490	180	80	290	600	80	30	…	10
Implant Radium Needles	700	430	90	360	470	90	…	…	…
Autopsy	150	140	60	…	…	35	…	…	…

Note: There was no legend for this table to explain the meaning for the abbreviation "Neg." or for the ellipsis (…). In addition, the Laparotomy procedure was not defined. The Medical Dictionary by the Editors of the American Heritage Dictionaries defines Laparotomy as a surgical incision into the abdominal cavity through the loin or flank.

From this table it is important to note the exposure to the hands compared to the whole body for these surgical procedures. The exposures to the hands were much higher than the total body.

The Medical Division used radiation-generating devices capable of delivering high doses of radiation to patients, and in the process, potentially exposing employees. Staff used teletherapy units that employed strong gamma emitters such as cobalt-60 and cesium-137 with large activities (200-800 curies) for the irradiation of cancerous organs, and for total body irradiations for leukemia treatment.

5.2.2 Internal Exposures

As indicated by the personnel interviewed during the evaluation, the ORINS Medical Division staff felt there was a low potential for significant internal exposure. This assumption was based on the short half lives of the isotopes used and the fact that these isotopes were used in liquid forms.

However, NIOSH's review of the documents in the SRDB and the documents obtained from the PubMed database identified a number of potential internal exposure scenarios at the ORINS Cancer Research Hospital. Although potential exposure scenarios would have differed depending on the radioisotopes involved, all scenarios would have shared the following common features: preparation of medicines containing radioisotopes for cancer treatment; administration of medicines to patients either orally or through injections; control and disposal of biological waste (e.g., urine, feces, cancerous organs and other contaminated waste); and exposure to, and control of, airborne contaminants created during spills of radioactive medicines and biological waste, especially iodine solutions.

These conclusions are corroborated by the following documented sources:

- A 1950 memo discussing external exposure concerns (MED-1950)
- Interview with a former ORINS Nurse employed during the class period (INT-2006)
- Medical reports retrieved from the PubMed database (AMA-1951, Rad-1980, HP-1985, HP-2005, and Thyroid-1997)

The 1950 memo (MED-1950) was written to identify the external exposure concerns from administering gallium to patients. However, the memo also identifies "associated problems" beyond the external exposure concerns. The first associated problem identified is general contamination of the facility:

> *Due to the manual handling, type of instruments required and unpredictable patient reactions, among other causes, infrequent major spills and more frequent minor spills are likely to occur. It appears common sense, great care and experience will have to point out the solutions as the incidents occur. It is most likely some rooms will have to be evacuated while spills are cleaned and allowed to decay. Monitoring of eating utensils, dishwasher, etc., appears to be a necessity as cases have already been noted.*

The second associated problem identified is exposure to contaminated urine:

> *Present samples are too contaminated for direct disposal in the sanitary sewer. They are being collected in bed pans for storage in one gallon jugs which are placed in an improvised shield for decay. They are eventually discharged into the hold up tanks provided. The room now used, which was not designed for the use, is practically filled and is also serving the purpose for which it was designed. Here again the probability of contamination due to spillage is high, although of much lower intensity than the original solution. This is likely to develop into a problem requiring additional facilities.*

The contamination problems identified above potentially exposed personnel to airborne contaminants that would lead to internal exposure. In addition, there was a potential for ingestion of radioactive contaminants from the contamination being spread to food, eating utensils, and other areas with a high potential for unprotected contact.

The issue of spills and the potential for internal exposures was discussed with a former ORINS nurse who worked during the class period. The nurse indicated that they tried to prevent spills, but they did occur. This nurse was contaminated and scrubbed down from a spill of contaminated urine.

In addition to the internal exposure potential associated with radiological incidents and provisional radiological safety procedures, potential internal exposure to radioiodine is a particular concern. During the period covered by this evaluation, medical practitioners did not recognize that radioiodine creates an airborne internal exposure hazard, which has since been widely documented (NCRP-1996, Rad-1980, HP-1985, HP-2005, and Thyroid-1997). NCRP Report No. 124 states:

> *Radioactive iodine has been noted for its volatility and therefore its potential for causing internal radiation dose in nuclear medicine personnel. Early (1987) and Miller (1979)*

reported that two to three percent of the liquid ^{131}I activity escaped when the cap of the bottle of liquid oral solution was removed as compared to 0.01 percent of the activity lost for iodine in the capsular form…

One of the PubMed reports evaluated iodine levels in the thyroid glands of all staff categories in a hospital laboratory (HP-1985). The highest level of iodine in this study, 40 microcuries, was found in the chemist who prepared the solutions. Another study found iodine activity in the thyroid gland in persons handling therapeutic doses of iodine-131 as high as 170-180 nCi when measured 24 hours later (Rad-1980). Although this does not present a significant dose for a single uptake, the dose will add up if chronically exposed. In addition, NIOSH does not have information to compare the levels of therapeutic doses in this study, in 1979, to those used at ORINS in the 1950s.

As indicated in Section 5.1, iodine-131 was used from the onset of ORINS Medical Division operations. The Division used iodine-125, -130, and -131 during the years identified in the proposed class description. Iodine-125 and -130 were used in the late1950s.

6.0 Summary of Available Monitoring Data for the Proposed Class

NIOSH reviewed the databases indicated in Section 4.0 for internal and external monitoring data. This includes personal monitoring data (e.g., film badges, TLDs, bioassays) and area monitoring data. NIOSH also attempted to gather data to support source term development.

6.1 External Monitoring

NIOSH's review of the claimant files in NOCTS showed that of the 11 claimants meeting the class definition, eight of them had film badge monitoring data. The data submitted to DOE for the EEOICPA program were either cards containing the external deep dose or the information transferred from the card to a table. The DOE records indicate that ORINS used the TLD-100 until 1999, and during the class period, the film was calibrated using radium as the source. One report (AMA-1951) indicated a weekly badge exchange, but that may have been for the study indicated. Most of the records received by NIOSH are annual summaries of external exposure. However, some of the records are monthly reads of the film badge. It appears from these records that a monthly read was the standard practice.

A request was made to ORAU (formerly ORINS) for additional external exposure data for ORINS employees within the class period. ORAU provided a spreadsheet with external monitoring data for ORINS employees from 1950-1961. The spreadsheet addressed external exposures to 504 ORINS employees. The external exposures provided by the DOE for the existing eight claimants with external dosimetry records were compared to the ORAU-provided spreadsheet; all of the numbers in the database matched the numbers provided by DOE. The external exposures listed in the spreadsheet were all deep dose. Table 6-1 was developed from the information in the spreadsheet.

Table 6-1: Summary of External Exposure Data Provided by ORAU				
Year	**No. Employees Monitored**	**Lowest dose recorded (mrem)**	**Mean dose recorded (mrem)**	**Highest dose recorded (mrem)**
1950	83	30	526	7051
1951	144	30	554	7310
1952	135	30	272	1090
1953	116	30	280	2675
1954	104	30	371	3901
1955	114	30	350	2330
1956	149	30	191	1210
1957	138	30	256	2305
1958	148	30	322	1360
1959	158	30	295	2215
1960	163	30	299	1355
1961	155	30	336	2845

Although beta emitters were used in a few applications during cancer research, it appears that Medical Division personnel would have had limited exposure to beta radiation. Based on interviews and the report, *Radioisotope Hazards and Protection in a Hospital* (AMA-1951), surgical gloves and other protective clothing would have limited the beta exposure to medical personnel. Additionally, that report includes a table that was recreated in Section 5.2.1 as Table 5-2. Table 5-2 provides support for the conclusion that there was a limited potential for beta exposure. The table includes exposures (open and closed window) to personnel in various job classifications over a three-month period. The open and closed window readings were very close to a 1:1 ratio.

The documents retrieved from the SRDB also were reviewed for external monitoring data. Dose rate information was found for a patient injected with 20 millicuries of gallium-67 (MED-1950) and area dose rate information for multiple injections occurring at the same time in the hospital.

6.2 Internal Monitoring

NIOSH has searched the data resources listed in Section 4.0 of this report and has not located any internal monitoring data for ORINS employees at the ORINS Cancer Research Hospital during the 1950-1963 period. This outcome is consistent with the reports of ORINS employees who have asserted there was no internal monitoring program during this period. Whole body monitoring data is available starting in 1964.

6.3 Air Sampling

NIOSH has searched the data resources listed in Section 4.0 of this report and has not located any air sampling data for ORINS Cancer Research Hospital during the 1950-1963 period. Again, the results of this data search are consistent with the reports of former employees.

6.4 Source Term

NIOSH reviewed available data sources for source term information. The SRDB contains ORINS annual reports for 1952-1959, 1962, 1963, and 1964. In 1953, 1954, 1962, and 1963 the reports listed isotopes and the amount of activity in millicuries used by the Medical Division for the year. For example, Table 6-1 identifies the isotopes and activity used by the Medical Division in 1954. This information was taken from the annual report titled, *Eighth Annual Report of the Oak Ridge Institute of Nuclear Studies,* dated June 30, 1954 (ORINS-1954).

Table 6-2: Isotopes Used by the ORINS Medical Division in 1954

Isotope	Activity (Millicuries)
antimony-121, 124	225
calcium-45	7
cesium-134	10
chromium-51	8
europium-152, 154	1.5
gallium-67	2587.4
gold-198	8275
holmium-166	64.3
iron-59	3.65
iodine-131	1350
lutecium-177	192
phosphorus-32	472
potassium-42	390
rubidium-86	145
sodium-24	12
sulfur-35	2
yttrium-90	82.6
yttrium-91	40
cobalt-60	275 Milligrams

7.0 Feasibility of Dose Reconstruction for the Proposed Class

The feasibility determination for the class of employees covered by this evaluation report is governed by EEOICPA and 42 C.F.R. § 83.13(c)(1). Under this Act and rule, NIOSH must establish whether or not it has access to sufficient information to either estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of the class, or to estimate the radiation doses of members of the class more precisely than a maximum dose estimate. If NIOSH were to have access to sufficient information for either case, then it would be determined that it was feasible to conduct dose reconstructions.

In making determinations of feasibility, NIOSH begins by evaluating whether current or completed NIOSH dose reconstructions demonstrate the feasibility of estimating with sufficient accuracy the potential radiation exposures of the class (presented in Section 7.5 of this report). In addition, NIOSH systematically evaluates the sufficiency of different types of monitoring data, process and source term data, which together or individually might assure NIOSH can estimate either the maximum doses that members of the class might have incurred, or more precise quantities that reflect the variability of exposures experienced by groups or individual members of the class. This approach is specified in the SEC Petition Evaluation Internal Procedures (OCAS-PR-004) available at www.cdc.gov/niosh/ocas.

Utilizing available personal and process monitoring data (see Section 5.0) to calculate maximum, claimant-favorable potential radiation doses for unmonitored employees is appropriate and possible only if the data are of sufficient quality. In addition to determining appropriate sampling, measurement, and analytical techniques, data quality sufficiency is dependant upon confidence that the *selection* of monitoring locations and personnel were appropriate and included the highest exposure locations and activities throughout the evaluated time frame. Similarly, it is important to determine that exposure potential associated with activities that were not associated with cancer treatment (e.g., research and development) were also evaluated.

Results of the evaluation efforts focused on historical personnel monitoring selection are presented in Section 7.1. Evaluations examining (separately) the availability of information necessary for reconstructing internal and external radiation doses of members of the class follow in Sections 7.2 and 7.3.

7.1 Analysis of Data Sufficiency and Reliability

Performing internal and external dose reconstructions requires worker monitoring data or source term and process information. Worker monitoring data includes data from members of the proposed class as well as data from workers outside the proposed class who were performing jobs with higher exposure potentials. Using co-worker monitoring data provides a means of calculating claimant-favorable and maximum potential radiation doses for class members who were unmonitored or have gaps in their monitoring records.

In the case of this evaluation, NIOSH has found that the internal monitoring data and source term are insufficient for estimating internal radiation doses with sufficient accuracy for members of the proposed class. Therefore, further evaluation of the pedigree of any of the data was not performed.

7.2 Internal Radiation Doses

The principal source of internal radiation doses for members of the proposed class would have been inhalation and ingestion of radiological contaminants during the following activities: (1) preparation of medicines containing radioisotopes for cancer treatment; (2) administration of medicines to patients either orally or through injections; (3) control and disposal of biological waste (e.g., urine, feces, cancerous organs and other contaminated waste); and (4) exposure to, and control of, airborne contaminants created during spills of radioactive medicines, especially iodine solutions.

As indicated in Section 6.2, there are not any internal monitoring data from the onset of operations in 1950 to 1964 when the whole body counter was installed. Internal monitoring data would allow direct reconstruction of an individual claimant's internal dose. Also, there are not any air monitoring data that could be used for an internal exposure model. Lacking these data, NIOSH considered the sufficiency of source term and process data for developing an internal exposure model for the ORINS employees covered by this evaluation. As indicated in Section 6.4, there are some source term data for 1953, 1954, 1962, and 1963. In addition to the annual source term information, source term information for specific cancer applications is available from 1964 through the end of operations. This information gives activities associated with each application, which allows a more detailed dose model to be developed.

Even though NIOSH has annual source term data for 1953, 1954, 1962, and 1963, there is no information defining how much activity of each isotope was used in each cancer treatment. Nor is there information as to how each isotope was administered. In lieu of bioassay data, this information is necessary to develop an exposure model with sufficient accuracy. There are indications that more information may be available, but at this time, NIOSH has been unable to obtain this information.

As a result of these limitations, NIOSH cannot establish a maximum internal exposure scenario that addresses all of the internal exposure potential for the petitioning class, and therefore, cannot estimate internal doses for members of this class with sufficient accuracy.

7.3 External Radiation Doses

The principal source of external radiation doses for members of the proposed class would have been due to exposures to photon (gamma) radiation. Photon exposures occurred from: (1) radioactive cocktails prepared and administered to patients; (2) removal and disposal of cancerous organs containing activities of radioisotopes; (3) care of patients containing activities of radioisotopes; and (4) radiation-generating devices used in cancer research.

Film badges were worn by all personnel from the onset of ORINS operations, including secretaries and janitors, as well as patient visitors, (AMA-1951). As indicated in Section 6.0, NIOSH's review of the claimant files in NOCTS showed that of the eleven claimants meeting the class definition, eight had film badge monitoring data. In addition, ORAU provided a spreadsheet with external monitoring data for ORINS employees from 1950-1961. The spreadsheet addressed external exposures to 504 ORINS employees. The data from the eight claimants with external exposure records was compared to this table and all eight claimants exposures matched.

If NIOSH has indication through CATIs or other reports that personnel may have had skin contamination, NIOSH will use computer programs like VARSKIN and other computer models to address the dose to the skin and other organs from skin contamination. Because the majority of the dose is from gamma exposure, a dose from a skin contamination to the body will be accounted for by the film badge, and any dose from a skin contamination to the extremities can be bounded by the extremity dose estimated from surgical procedures.

NIOSH finds that the available external monitoring data should be sufficient to reconstruct the external doses of all members of the proposed class.

ORINS Cancer Research Hospital Occupational X-ray Examinations

As revealed in the NIOSH review of the current individual claims and the SRDB, very little information exists concerning medical X-rays at ORINS during the class period. Based on one of the claims, chest X-rays were performed for routine physicals. However, the periodicity of X-rays is not clear; additional interviews may provide more detailed information concerning this issue. Once these interviews are complete, a reasonable periodicity can be identified. Using the identified periodicity, an upper bound for exposure for occupational medical X-rays can be established using the procedure, *Occupational X-Ray Dose Reconstruction for DOE Sites* (ORAUT-PROC-0061).

In summary, NIOSH can reconstruct the medical X-ray dose for the class of ORINS workers in the class defined in this evaluation report with sufficient accuracy.

7.4 Evaluation of Petition Basis for SEC-00033

The petition basis provided in SEC-00033 was that there was no internal monitoring of personnel from June 1, 1950, to June 25, 1956.

Personal monitoring, area monitoring, or co-worker monitoring are not always required in order to develop an exposure model for a given facility. However, if these are not available, NIOSH must have access to source term information and detailed process information in order to develop a sufficiently accurate exposure model. NIOSH has some source term information for 1953, 1954, 1962, and 1963, but not enough source term or process information to develop a sufficiently accurate model for all of the radionuclides used in the cancer research facility. Therefore, NIOSH concludes there is insufficient information to reconstruct internal doses with sufficient accuracy and that the petition basis has been supported.

7.5 Summary of Feasibility Findings for Petition SEC-00033

This report evaluated the feasibility for completing dose reconstructions for Medical Division employees at ORINS from May 15, 1950, through December 31, 1963. NIOSH found that the monitoring records, process descriptions, and source term data available are not sufficient to perform complete dose reconstructions for the proposed class of employees. Specifically, NIOSH has determined that data to support reconstruction of internal dose does not exist. However, NIOSH has determined that external dose and medical x-ray dose can be reconstructed with sufficient accuracy.

Table 7-1 summarizes the results of the feasibility findings at Site Name for each exposure source for the time period May 15, 1950 through December 31, 1963.

Table 7-1: Summary of Feasibility Findings for SEC-00033

Source of Exposure	Reconstruction Feasible	Reconstruction Not Feasible
Internal		X
External	X	
Occupational Medical X-ray	X	

8.0 Evaluation of Health Endangerment for Petition SEC-00033

The health endangerment determination for the class of employees covered by this evaluation report is governed by EEOICPA and 42 CFR § 83.13(c)(3). Under these requirements, if it is not feasible to estimate with sufficient accuracy radiation doses for members of the class, NIOSH must also determine that there is a reasonable likelihood that such radiation doses may have endangered the health of members of the class. The regulation requires NIOSH to assume that any duration of unprotected exposure may have endangered the health of members of a class when it has been established that the class may have been exposed to radiation during a discrete incident likely to have involved levels of exposure similarly high to those occurring during nuclear criticality incidents. If the occurrence of such an exceptionally high level exposure has not been established, then NIOSH is required to specify that health was endangered for those workers who were employed for a number of work days aggregating at least 250 work days within the parameters established for the class or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

This NIOSH evaluation did not identify any evidence from the petitioners or from other resources that would establish that the class was exposed to radiation during a discrete incident or similar conditions resulting from the failure of radiation exposure controls and likely to have produced levels of exposure similarly high to those occurring during nuclear criticality incidents. NIOSH is not aware of any report of such an occurrence at the facility during this period. NIOSH finds the primary radiation exposure hazards to employees resulted from chronic exposures from the inhalation and ingestion of radionuclides, combined with external exposures to gamma and beta radiation. Consequently, NIOSH is specifying that health was endangered for those workers covered by this evaluation who were employed for a number of work days aggregating at least 250 work days within the parameters established for this class or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

9.0 NIOSH Proposed Class for Petition SEC-00033

This evaluation defines a single class of employees for which NIOSH cannot estimate radiation doses with sufficient accuracy. This class includes: *Employees of the DOE or DOE contractors or subcontractors who were monitored, or should have been monitored, while working at the Oak Ridge Institute of Nuclear Studies Cancer Research Hospital from May 15, 1950, through December 31, 1963, and who were employed for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days within the parameters (excluding aggregate work day parameters) established for other classes of employees included in the SEC.*

This page intentionally blank

10.0 References

AMA-1951, *Radioisotope Hazards and Protection in a Hospital*, Marshall Brucer, M.D.; Journal of the American Medical Association; December, 1951

Chem-1980, *Advantages of Using Thin Sodium Iodide Detectors for Thyroid Monitoring of Personnel Working with ^{125}I ,* Clinical Chemistry; January, 1980

HP-1962, *A Summary of Radiation Exposures Received by Workers in Medical X-ray Departments from 1950-1960,* Health Physics; March 1962

HP-1985, *Thyroid Burdens of ^{125}I in Laboratory Workers*, Health Physics; June, 1985

HP-2005, *A Case Study of the Estimation of Occupational Internal Dose using Urinary Excretion Data Obtained in a Biomedical Research Facility*, Health Physics; December, 2005

HP-1999, *Experiences with High Dose Radiopeptide Therapy: The Health Physics Perspective*, Health Physics; March, 1999

INT-2006, Interview with former ORINS nurse; SECIS document ID: 2004 5/19/2006 (Non-submitter communication)

MED-1950, *ORINS Medical Center Radiation Problem*; Office Memorandum – United States Government; August 15, 1950; Oak Ridge Associated Universities; Oak Ridge, TN

NCRP-1996, NCRP Report No. 124, *Sources and Magnitude of Occupational and Public Exposures from Nuclear Medicine Procedures,* NCRP; March 1996

NucMed–Jun2003, *Safe Radiation Exposure of Medical Personnel by using Simple Methods of Radioprotection while Administering ^{131}I-Lipiodol Therapy for Hepatocellular Carcinoma,* Nuclear Medicine Communications; June 2003

NucMed-May2003, *Is it Safe to Work with Iodine-131 if You are Pregnant? A Risk assessment for Nuclear Medicine Staff Involved with Cleaning and Decontamination,* Nuclear Medicine Communications; May 2003

NucTech-2002, *Measuring and Minimizing the Radiation Dose to Nuclear Medicine Technologists,* Journal of Nuclear Medicine Technology; March 2002

OCAS-PR-004, *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions*, Rev. 0, National Institute for Occupational Safety and Health (NIOSH); Cincinnati, Ohio; September 23, 2004

ORAU-1949, Oak Ridge Associated Universities website, http://www.orau.org/visitor/history/chronology/1949.htm

ORAU-1950, Oak Ridge Associated Universities website, http://www.orau.org/visitor/history/chronology/1950.htm

ORAUT-OTIB-0006, *Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*; Rev. 3, PC1; December 21, 2005

ORAUT-PROC-0061, *Occupational X-Ray Dose Reconstruction for DOE Sites*; Rev. 00, December 1, 2004

ORINS-1952, *Sixth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1952; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1953, *Seventh Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1953; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1954, *Eighth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1954; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1955, *Ninth Annual Report of the Oak Ridge Institute of Nuclear Studies*, June 30, 1955; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1956, *Tenth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1956; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1957, *Eleventh Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1957; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1958, *Twelfth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1958; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1959, *Thirteenth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1959; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1960, *Fourteenth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1960; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1962, *Sixteenth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1962; Oak Ridge Associated Universities; Oak Ridge, TN

ORINS-1963, *Seventeenth Annual Report of the Oak Ridge Institute of Nuclear Studies*; June 30, 1963; Oak Ridge Associated Universities; Oak Ridge, TN

Rad-1980, *Internal Contamination of Laboratory Personnel by ^{131}I,* Radiology (journal); December, 1980

Thyroid-1997, *Regulations for Radioiodine Therapy in the United States: Current Status and the Process of Change*, Thyroid; April 1997