

OFFICE OF THE SECRETARY  
CORRESPONDENCE CONTROL TICKET

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To: ~~EDO~~ Lohaus, STP

AUTHOR: Paul Schmidt

AFFILIATION: WI

ADDRESSEE: Paul Lohaus

SUBJECT: Supplemental information to Wisconsin's Final Agreement State Application

CYS: EDO  
DEDMRS  
DEDR  
DEDM  
AO  
R111

ACTION: Information

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**State of Wisconsin**  
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January 6, 2003

Paul H. Lohaus, Director  
Office of State and Tribal Programs  
U.S. Nuclear Regulatory Commission  
11555 Rockville Pike OWFN-3C10  
Rockville, MD 20852

03 JAN -7 PM 2:45  
STP

Dear Mr. Lohaus:

The Department of Health and Family Services (DHFS) has received the NRC evaluation of Wisconsin's Final Agreement State Application. In your letter dated December 16, 2002, you have requested a response to four comments identified by the NRC review team that evaluated Wisconsin's final application. The DHFS response to each of these comments is as follows:

**Comment 1: Qualifications of Regulatory and Inspection Personnel**

**Response:** The State of Wisconsin, Department of Health and Family Services has an adequate number of fully qualified staff for each license category to independently license, inspect and regulate the use of byproduct, source and special nuclear material on the effective date of the agreement. Current, fully qualified staffing levels include:

- 1.0 FTE Materials Program Supervisor
- 4.5 FTE Nuclear Engineers
- 1.25 FTE Program Assistant

The Materials Program Supervisor has thoroughly analyzed the inspection workload based on the number and types of specific licenses in Wisconsin. This analysis indicates an average inspection workload of 137 inspections per year. An analysis of the inspection workload for the first year of the agreement, however, indicates that a total of only 55 inspections are due, including 25 Priority I's. Each fully qualified staff member will conduct 10 inspections, including 5 Priority I's. The Wisconsin Training and Qualification Plan, discussed in greater detail below, has been used to evaluate and fully qualify the staff identified above. These fully qualified staff members also provide an initial, adequate level of staffing to satisfactorily handle anticipated licensing, reciprocity, allegations and incident response workload.

In addition to the fully qualified staff indicated above, the radioactive materials program has:

- 1.0 FTE Nuclear Engineer on staff that will be fully qualified by September, 2003 (three months after the effective date of the agreement).
- 0.5 FTE Nuclear Engineer on staff dedicated to training and procedure/rule development.
- 1.0 FTE Nuclear Engineer position vacancy that we expect to fill by February, 2003 and be fully qualified by December, 2003 (six months after the effective date of the agreement).
- Requested an additional 0.25 FTE Program Assistant to complete the planned technical and administrative staffing level of 9.5 FTE.

A fully qualified and experienced materials program supervisor has developed and implemented the Wisconsin Training and Qualification Plan. Each Nuclear Engineer's training and experience was evaluated by the materials program supervisor and the results documented in each individual's Nuclear Engineer Qualifications Journal, (see RMPP 6.01, Qualifications and Training.). The radioactive materials program staff have completed extensive formal and on-the-job training leading to full qualification. This training includes:

- NRC core courses (see Agreement State application)
- NRC inspector accompaniments
- NARM inspections
- License reviews (1 week minimum) at NRC Region III
- Licensing exercises to illustrate use of HFS 157
- Assisting other agreement states with inspections (e.g., Iowa)
- Gamma-knife training at the Mayo Clinic, Rochester, MN
- Specialized in-house training including 10 CFR 20, HFS 157 overview, management of allegations, incident response and regulatory guides

Program Assistants have also completed specialized in-house training for their position responsibilities. Training includes computer database operation, legal record requirements and exposure reporting. See Attachment 1 for the requested staff resource analysis that shows individual Nuclear Engineer names and projected workload.

#### **Comment 2: Inspection and Enforcement**

**Response:** The DHFS, Radiation Protection Section (RPS) currently has adequate numbers and types of calibrated radiation survey instruments to perform radiation monitoring during inspections, investigations, incident response and other regulatory activities. See Attachment 2 for the Radiation Protection Section Instrument Calibration and Quality Assurance Program.

#### **Comment 3: Licensing**

**Response:** The Department will accept Radiation Safety Officers who have completed a 3-day RSO training course. DHFS will revise the industrial radiography license application form to delete the "40 hour" requirement for additional RSO training.

**Comment 4: Events and Allegations**

**Response:** See Attachment 3 for requested copies of the final, approved procedures titled "RMPP 4.01 – Management of Allegations" and "RMPP 4.02 – Radiological Incident Response".

Finally, concerning your comments on HFS 157 'Radiation Protection' as outlined in your November 27, 2002 letter, DHFS provided a complete response to all comments, including rule comment number 12, in a separate letter dated December 12, 2002.

If you have any questions about this letter or any of the attachments, please contact Cheryl Rogers at 608 266-8135 or [rogerck@dhfs.state.wi.us](mailto:rogerck@dhfs.state.wi.us) or myself at 608 267-4792 or [schmips@dhfs.state.wi.us](mailto:schmips@dhfs.state.wi.us).

Sincerely,



Paul Schmidt, Chief  
Radiation Protection Section

Attachment 1

# STAFF RESOURCE ANALYSIS

Staff Member	Jason Hunt		Paul Caleb		Mike Mack		Leola DeKock		Michael Welling		Rashid Salikhdjan.		Vacant		TOTAL	TOTAL
License Category	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic
Broadscope – Medical (I)	11	12	12	12	12		10	12	10	12	10	12	10	12	75	72
Broadscope – Academic (I)	12	12	11	12	12		10	12	10	12	10	12	10	12	75	72
Industrial Radiography (I)	20	6	20	6	20		25	5	25	5	25	5	25	5	160	32
Nuclear Pharmacy (I)	19	4	19	4			19	4	19	4	19	4	19	4	114	24
HDR (I)	1	1	1	1			2	0	2	0	2	0	2	0	10	2
Mobile Nuc-Med (II)	6	3	6	3			7	3	7	3	7	3	7	3	40	18
Gamma Knife – Teletherapy (III)	1	1	1	1			1	0	1	0	1	0	1	0	6	2
Medical – Diagnostic (III)	9	9	9	9			9	9	9	9	9	9	9	9	54	54
Medical – Therapy (III)	22	22	22	22			22	22	22	22	22	22	22	22	132	132
Manufacturing with Distribution (III)	1	0	1	0		4	1	0	1	0	1	0	1	0	6	4
IN-Vitro Testing (V)	1	1	1	1			0	0	0	0	0	0	0	0	2	2
Fixed Gauges (V)	5	4	5	4	6	2	6	4	6	4	6	4	6	4	40	26
Portable Gauges (V)	14	7	14	7	40	2	10	13	10	13	10	13	10	13	108	68
Research & Development (V)	5	4	5	4	4		4	2	4	2	4	2	4	2	30	16
Self Shielded Irradiators (V)	2	0	2	0			1	1	1	1	1	1	1	1	8	4
Source Material (V)	0	1	0	1	3		0	0	0	0	0	0	0	0	3	2
Other – NARM (V)	3	2	3	2	3		0	1	0	1	0	1	0	1	9	8
Other (V)	3	0	3	0	2		4	5	4	5	4	5	4	5	24	20
Reciprocity	6		6		6		5		5		5		5		38	
<b>TOTAL</b>	<b>141</b>	<b>89</b>	<b>141</b>	<b>89</b>	<b>108</b>	<b>8</b>	<b>136</b>	<b>93</b>	<b>136</b>	<b>93</b>	<b>136</b>	<b>93</b>	<b>136</b>	<b>93</b>	<b>934</b>	<b>558</b>

Attachment 2

**Radiation Protection Section  
Instrument Calibration and Quality Assurance Program**

Dosimetry

- A. Optically stimulated luminescent (OSL) dosimeters are used to determine legal record radiation exposure of staff. OSL dosimeters are provided and processed by Landauer, Inc., a NVLAP accredited dosimetry processor. OSLs are exchanged on a monthly basis.
- B. Self-reading dosimeters (SRDs) are used, as necessary, to provide an estimate of accrued radiation exposure. SRDs are calibrated and drift-checked annually by the University of Wisconsin Radiation Calibration Laboratory located in Madison, WI. The U.W. calibration laboratory is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association of Physicists in Medicine (AAPM), and uses sources directly traceable to National Institute of Standards and Technology (NIST) primary standards.
- C. SRDs that fail calibration or drift check tests are immediately disposed of.

Field Instruments

- A. Beta/gamma survey instruments are annually calibrated by the University of Wisconsin Radiation Calibration Laboratory located in Madison, WI. The U.W. Calibration Laboratory is accredited by NVLAP and the American Association of Physicists in Medicine, and uses sources directly traceable to NIST primary standards. They are currently licensed by the NRC.
- B. Alpha survey instruments are calibrated annually by the University of Wisconsin Radiation Safety Department.
- C. Neutron survey instruments (REM ball) are calibrated annually by the manufacturer, Eberline, Inc.
- D. Reuter-Stokes pressurized ion chambers, used to conduct environmental gamma radiation surveys, are annually calibrated by the manufacturer, G. E. Reuter-Stokes, Inc.
- E. All field survey instruments have a calibration sticker placed on them to indicate the calibration-done and calibration-due dates.
- F. A field instrument may not be used unless the date of proposed use is within 1 year of the date of last calibration.
- G. Field instruments are battery-checked and response-checked with an appropriate check source at the beginning of each day of use.
- H. The RPS maintains an inventory and calibration status log of all field survey instruments.
- I. A RMP Nuclear Engineer has been assigned responsibility in their position description to maintain the RPS Instrument Calibration and Quality Assurance Program and ensure there are operable and calibrated survey instruments available for use at all times.

## Laboratory Instruments

- A. The Department of Health and Family Services, Radiation Protection Section (RPS) maintains, calibrates and operates an intrinsic germanium detector to analyze environmental samples and samples of unknown radioactive materials for isotope identity and quantity.
- B. The intrinsic germanium analysis system is calibrated annually and after major component repair or replacement using NIST traceable calibration standards and calibration procedures.
- C. Linearity and efficiency checks are performed biweekly and at the beginning of each day of use.
- D. The RPS participates in a cross-check program operated by the Dept. of Energy. DOE provided samples are analyzed on the RPS germanium analysis system for radioactive content. The RPS analysis results are compared against the known isotope identity and quantity of the cross-check samples.
- E. The primary Nuclear Engineer assigned to maintain, calibrate and operate the system has received extensive training in gamma isotopic analysis from the manufacturer of the system.
- F. The RPS has developed and uses sample preparation and analysis procedures to ensure consistent and accurate results.

Attachment 3

**STATE OF WISCONSIN  
HEALTH AND FAMILY SERVICES**

**Radiation Protection Section**

**Radiation Protection Procedure No. 4.01**

**Management of Allegations**

Prepared By: Paul J. Caleb Date 1/3/03  
Paul J. Caleb

Reviewed By: Cheryl K. Rogers Date 1/3/03  
Cheryl K. Rogers, Materials Program Supervisor

Reviewed By: Mark C. Bunge Date 1-6-03  
Mark C. Bunge, X-Ray Program Supervisor

Approved By: Paul S. Schmidt Date 1-6-03  
Paul S. Schmidt, Radiation Protection Section Chief

Effective Date: 1-6-03

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## 1.0 PURPOSE

### 1.1 Applicability

This procedure is to ensure that allegations made against a licensee or registrant are properly addressed. Actions taken in response to an allegation include investigation, documentation and enforcement, as appropriate.

### 1.2 References

1.2.1 NRC Management Directive 8.8, "Management of Allegations"

1.2.2 NRC Handbook 8.8, "Management of Allegations"  
Handbook 8.8 contains detailed guidelines and procedures for the management and processing of allegations.

1.2.3 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program"

1.2.4 Radioactive Materials Program Procedure, No. 3.05, "Enforcement, Escalated Enforcement, and Administrative Actions"

1.2.5 Wisconsin Statute 19.32-39 (Open Records Law)

1.2.6 Chapter HFS 157, 'Radiation Protection'

### 1.3 Computer Based Letters, Forms, and Reports

1.3.1 Allegation Management System (AMS)

1.3.2 Blank report forms and log

### 1.4 Hardcopy Files

1.4.1 Allegation File (AF)

### 1.5 Definitions

1.5.1 Allegation means a declaration, statement or assertion of impropriety or inadequacy associated with Radiation Protection Section regulated activities, the validity of which has not been established. This term includes all concerns identified by individuals or organizations regarding activities at a registrant's, licensee's or applicant's facility. Excluded from this definition are inadequacies provided to RPS staff members by licensee's managers acting in their official capacity.

- 1.5.2 Allegation File (AF) means a secure hardcopy file that contains the documentation concerning the allegation
- 1.5.3 Allegation Management System (AMS) means a secure computerized system that contains a summary of significant data pertinent to each allegation.
- 1.5.4 Alleger means an individual or organization that makes an allegation. The alleger may be known or anonymous.
- 1.5.5 Confidentiality means the protection of the alleger's identity. Under Wisconsin State law, every effort will be made to protect information that could directly or otherwise identify an individual by name and/or the fact that a confidential source provided such information to the RPS.
- 1.5.6 Confidential Source means an individual who requests and, to the extent possible, is granted confidentiality in accordance with state procedures.
- 1.5.7 Investigation means, for purposes of this procedure, a special activity conducted by the program and used to evaluate and resolve an allegation.
- 1.5.8 Overriding Safety Issue means an immediate threat to public health, safety, or security, warranting immediate action by the licensee or registrant to evaluate and address the issue.
- 1.5.9 Requirement means a statute, rule, license condition or order.
- 1.5.10 Secure Files means files that are locked when not in use and for which access is controlled on a need-to-know basis.
- 1.5.11 Willfulness means a characteristic of a licensee's or registrant's actions whereby violations result from deliberate intent to falsify documentation pertaining to license requirements, to violate license or registration requirements, or from careless disregard for license or registration requirements.
- 1.5.12 Wrongdoing means either an intentional violation of requirements or a violation resulting from careless disregard of or reckless indifference to requirements.

## **2.0 RESPONSIBILITIES**

### **2.1 Radiation Protection Section staff**

Any Radiation Protection Section staff member is responsible for recording the initial allegation, any contact information provided and immediately referring the allegation to the appropriate program supervisor or the Section Chief.

### **2.2 Nuclear Engineer / Radiation Engineering Specialist**

When designated as the Lead Investigator (LI), coordinates the processing of an allegation. Performs the investigation of the allegation and prepares all records and reports concerning the allegation.

### **2.3 Program Assistant**

Develops and implements the Allegation Management System and the Allegation File (AF).

### **2.4 X-Ray or Materials Program Supervisor**

Manages the development and implementation of the Allegation Management Program (AMP), manages the AMS and conducts periodic reviews of the program. Informs the Section Chief of all AMP activity. Recommends appropriate actions to Section Chief in response to allegations.

### **2.5 Section Chief**

Reviews recommendations made by the X-Ray or Materials Program Supervisor and approves actions to be taken in response to allegations. Authorizes the release of the identity of alleged(s) and confidential sources. Requests legal assistance, if required. Directs the AMP, as appropriate. Informs the Bureau Director of the allegations and proposed actions to be taken in response to the allegations.

## **3.0 PROCEDURE**

### **3.1 Initial Contact**

**Note:** The alleged's identity, or information that could reveal that identity, should be imparted to section staff on a need-to-know basis and should not be revealed to personnel outside the Radiation Protection Section. All documentation pertaining to the allegation shall be securely stored. Files will be computer password secured and hard copy files will be returned to secure files when not in use. See attachment 4.01-4.

**Note:** Allegations regarding suspected improper conduct by a Radiation Protection Section employee do not fall within the scope of this procedure and shall be promptly reported to the employee's immediate supervisor.

- 3.1.1 Obtain and record as much information as possible from allegor on the Initial Contact Phone Log (see Attachment 4.01-1).
- 3.1.2 If the allegation involves discrimination under Section 211 of the Energy Reorganization Act (age, sex, race, etc.), then refer the allegor to the Equal Rights Division in the Department of Workforce Development.
- 3.1.3 If the allegor refuses to provide his/her name or other form of identification, then obtain as much information as possible and advise the allegor that he/she may contact the X-Ray or Materials Program Supervisor in 30 working days for information regarding the response to the allegation.
- 3.1.4 Address the issue of confidentiality with the allegor in accordance with section 3.2.
- 3.1.5 Inform the appropriate program supervisor of the allegation and submit completed Attachment 4.01-1.

### **3.2 Disclosure of Allegor's Identity.**

**Note:** The RPS will make all reasonable efforts to maintain confidentiality of the allegor's identity; however, the RPS cannot guarantee confidentiality. Disclosure of an allegor's identity may be made in accordance with 3.2.2 and 3.2.3 below.

- 3.2.1 Prior to terminating initial contact (see 3.1) with an allegor, inform the allegor of the degree to which their identity can be protected, including the following:
  - The allegor's identity and information that would reveal that identity will be withheld from RPS staff except on a need-to-know basis.
  - All information regarding the allegor's identity will be stored in a secure file under the control of the MPS.
  - Inspection reports and correspondence to licensees, other Agreement States, Federal Agencies (including NRC), other organizations or individuals will contain no information that could lead to the identification of the allegor or confidential source.

- The alleged's identity or information regarding the alleged's identity will not be disclosed outside of RPS, except under the conditions stipulated in section 3.2.2.

3.2.2 Inform the alleged that disclosure of his or her identity may occur if:

- The alleged has clearly indicated no objection to being identified.
- Disclosure is necessary because of an overriding safety issue.
- Disclosure is necessary pursuant to a legal order.
- Disclosure is necessary to continue a wrongdoing investigation, including an investigation of a discrimination allegation.
- Disclosure is necessary to support a hearing on an enforcement matter.
- The alleged has taken actions that are inconsistent with and override the purpose of protecting the alleged's identity.
- Disclosure is mandated by Wisconsin's Open Records law.

3.2.3 If the alleged's identity must be disclosed, then obtain approval from Section Chief prior to disclosure.

3.2.4 If the allegation is received by means other than telephone and the alleged's identity is known, then inform the alleged, by letter within 10 working days of the degree to which his or her identity can be protected as described in 3.2.1 – 3.2.3. See Attachment 4.01-5.

3.2.5 If requested by the alleged, then inform the alleged that a Non-disclosure Statement (Attachment 4.01-2) is available and will be sent within 10 working days.

### 3.3 Controlling Allegations

**Note:** Allegations should be addressed according to the guidelines listed below:

- Overriding safety issue – shall be addressed immediately
- High safety significance - should be addressed expeditiously, usually within 30 working days
- Low safety significance - should be addressed as priorities and resources permit, usually within 6 months of receipt.

### 3.3.1 Action by the Program Supervisor.

- Appoint a Lead Investigator (LI) for the allegation (See subparagraph 3.3.2).
- Ensure an AF is opened for the allegation and entered in the AMS.
- With the assistance of the LI, perform an immediate assessment of the allegation in accordance with Attachment 4.01-3 to determine if an overriding safety issue exists.
- If multiple allegations are made, broaden the scope of the evaluation to determine the extent of the problem.
- If an overriding safety issue exists, immediately convene a review group consisting of the Program Supervisor, the Section Chief or the Bureau Director, the LI and a member of the legal staff, as available.
- If no overriding safety issue exists, as soon as possible but within 30 calendar days, convene a review group consisting of the Program Supervisor, the Section Chief or the Bureau Director and the LI. The Program Supervisor may include a member of the legal staff.
- Ensure findings of the review group are entered into the appropriate AF.

**Note:** All discussion with the legal representative on the review group concerning suspected wrongdoing shall be documented, stamped confidential and filed separately within the AF.

- As necessary, brief the Bureau Director on the review group's findings and recommendations.

### 3.3.2 Evaluation by Lead Investigator

- In consultation with the Program Supervisor, perform an immediate assessment of the allegation in accordance with Attachment 4.01-3 to determine if an overriding safety issue exists.
- Determine, in conjunction with the Program Supervisor and review group, the actions necessary for resolution of the allegation.
- Identify additional resources required for resolution of the allegation.
- Develop a schedule for the resolution of each allegation consistent with the inspection schedule.

- With the approval of the Program Supervisor, implement actions necessary for resolution of the allegation.

**Note:** Follow-up of allegations should focus not only on the particular allegation but also on the overall area of concern, including the potential for generic implications and wrongdoing.

### 3.4 Referral of Allegations to Licensees

The decision whether or not to refer an allegation to the licensee or registrant will be made upon the recommendation of the LI with the approval of the Program Supervisor, and based on the considerations delineated in 3.4.1 and 3.4.2.

#### 3.4.1 Prohibitions on Referrals

**Note:** If an allegation raises an overriding safety issue, the substance of the allegation will be released to the licensee or registrant, regardless of the need to protect the identity of the alleger or the confidential source, if release or the information is necessary to protect public health, safety, or security. The 30-day waiting period (see subsection 3.4.3 following) may be waived if the alleger or confidential source cannot be reached in a timely manner.

**Do not** refer the allegation to the licensee or registrant if any of the following apply:

- The identity of the alleger or confidential source, who has requested protection of anonymity, would be compromised by the information released to the licensee or registrant.
- The evaluation of the allegation would be compromised because of knowledge gained by the licensee or registrant from information released to the licensee or registrant.
- The allegation is made against the licensee's or registrant's management or those parties who would normally receive and address the allegation.
- The allegation is based on information received from a Federal agency that does not approve of the information being released to the licensee or registrant.
- The alleger has previously addressed the allegation with the licensee or registrant with unsatisfactory results and the alleger objects to a referral.

### 3.4.2 Referral Criteria

Consider the following when determining whether to refer an allegation(s) to a licensee or registrant:

- Could the release of information bring harm to the allegor or confidential source?
- Has the allegor or confidential source objected to the release of the allegation to the licensee or registrant?
- What is the licensee's or registrant's history of addressing allegations? What is the likelihood that the licensee or registrant will effectively investigate, document and resolve the allegation?

### 3.4.3 Informing the Allegor

**Note:** The Program Supervisor or designated staff shall be responsible for informing the allegor or confidential source of the RPS' intent to refer the allegation to the licensee or registrant.

- Prior to referring an allegation to a licensee or registrant, make all reasonable efforts to inform the allegor or confidential source of the intent to refer.
- Provide the initial notification to the allegor by phone and document with a letter to the allegor. Include in the notification that the RPS will evaluate the licensee's or registrant's activities and response and that the allegor or confidential source will be informed of the final disposition of the allegation.
- If the allegor or confidential source cannot be reached by telephone, then inform the allegor or confidential source by letter of the intent to refer the allegation to the licensee.
- If the allegor or confidential source objects to the referral, or does not respond to the letter within 30 calendar days, and the factors described in sections 3.3.1 and 3.3.2 have been considered, then refer the allegation to the licensee or registrant.

### 3.4.4 Referral Letter

**Note:** The Program Supervisor or designated staff shall be responsible for submitting a referral to the licensee or registrant.

- If a referral of an allegation is to be made to the licensee or registrant, then

ensure the referral letter contains the following:

- A complete description of the elements of the allegation, excluding the identity of the allegor or confidential source, or any information that could result in the licensee or registrant identifying the allegor or confidential source.
  - A statement that the referral is a result of an allegation against the licensee or registrant.
  - A request to the licensee or registrant to thoroughly review the elements of the allegation in a manner that is objective, of sufficient scope and of sufficient depth to resolve the allegation.
  - A request for a written report of the results of the review, to be submitted to the RPS within 10 working days of receipt by the licensee or registrant of the referral letter.
- If the allegation was received in writing, then do not include a copy or the original written information from the allegor or confidential source in the written referral to the licensee or registrant, unless written permission from the allegor or confidential source has been obtained.
  - Ensure a copy of the referral letter is entered into the AF.

#### 3.4.5 Licensee or Registrant Response

**Note:** The Program Supervisor is responsible for determining whether the licensee or registrant response is adequate and for directing further actions to be taken in response to the licensee's review of an allegation.

- Evaluate the adequacy of licensee's or registrant's response considering, at a minimum, all the following factors:
  - Was the evaluation conducted by an entity independent of the organization in which the alleged event occurred?
  - Was the evaluator competent in the specific functional area in which the alleged event occurred?
  - Was the evaluation of adequate depth to establish the scope of the problem?

- Was the scope of the evaluation sufficient to establish that the alleged event or problem was not a systemic defect?
- If the allegation was substantiated, did the evaluation consider the root cause and generic implications of the allegation?
- Was the licensee's or registrant's corrective action sufficient to prevent, alleviate, or correct deficiencies in both the specific and generic instances, and in the short and long term?
- If the licensee's or registrant's response is adequate, then notify the licensee within 10 working days that the response is adequate and that no further action is required. The response will be incorporated in the closeout letter to the allegor or confidential source and documented in the AMS.
- If the licensee's or registrant's response is considered to not be adequate, then determine the additional actions required to resolve the allegation.
- Ensure a copy of both the licensee's or registrant's response and the RPS response letter are entered into the AF.

### 3.5 Investigations

**Note:** If the allegation cannot be referred to the licensee or registrant (See subsection 3.4.1); is not resolved by the licensee or registrant; or, involves possible wrongdoing (willfulness) an investigation shall be performed, preferably by the LI. The investigation may be included as part of a routine inspection or may involve only the allegation(s).

- When conducting an investigation in response to an allegation, use all the following techniques:
  - Inspect the issue not the allegor or confidential source.
  - Avoid prejudice.
  - Do not communicate that the specific issue was raised by an allegor or confidential source (See subsection 3.4.4).
  - Take extensive notes and obtain copies of pertinent records, if possible.
  - Interview employees regarding relevant procedures and activities.
  - Verify any assertions made by the licensee or registrant.

- Document the results of the investigation in a written report and submit to Program Supervisor.
- Ensure a copy of the investigation report is entered into the AF.

**Note:** Any recommended enforcement action must be approved by the Section Chief and shall be addressed in accordance with RMPP No. 3.05 "Enforcement, Escalated Enforcement and Administrative Actions".

#### **4.0 RECORDS**

##### **4.1 Hardcopy**

The Allegation File (AF) is a secure file that contains the hardcopy documentation concerning the allegation.

##### **4.2 Computer Based**

The Allegation Management System (AMS) is a secure computerized system that contains a summary of significant data pertinent to each allegation.

#### **5.0 ATTACHMENTS TO RMPP No. 4.01**

- 4.01-1 Initial Contact Phone Log**
- 4.01-2 "Nondisclosure Statement" – Example**
- 4.01-3 Allegation Screening Form**
- 4.01-4 Confidential Information and Files**
- 4.01-5 Acknowledgement Letter to Allegor**

**INITIAL ALLEGATION CONTACT PHONE LOG**

**INSTRUCTIONS:**

This log is to be used to record the information gathered in an Allegation against a licensee or registered user.

Inform the individual of the conditions regarding confidentiality.

YES – the individual was notified

Individual has requested confidentiality.

Individual has declined confidentiality.

**ALLEGER INFORMATION –**

Individual's Full Name:

Telephone number :

Position or relationship to the facility or activity involved:

Alleger's Employer:

Home mailing address:

Facility / location:

What sort of activities or practices did this involve? What have they observed?

**Nature and Details of the Allegation –**

How long has this activity been occurring?

Why do they believe this to be a safety concern?

Is this a current or past unsafe practice?

How did the individual find out about the concern?

Date(s) and times of Occurrence –

Are there other individuals who should be contacted for additional information?  
(list names, addresses, phone number if available)

What records does the individual think should be reviewed?

Has the individual raised the concerns with his/her management?

Yes What action has been taken?

No If no, why not?

**\*\*If the allegation involves discrimination under Section 211 of the Energy Reorganization Act (age, sex, race, etc.) inform the alleger that they should contact the Equal Rights Division in the Department of Workforce Development.\*\***

**Actions to be taken -**

Refer this to the appropriate program supervisor.

Materials program supervisor

X-ray program supervisor

If this issue was referred to another agency please list the name of agency :



**Attachment 4.01-2  
Nondisclosure Statement-Example**

I have information that I wish to provide in confidence to the Wisconsin Department of Health and Family Services (DHFS), Radiation Protection Section (RPS). I request that the DHFS, Radiation Protection Section not reveal that I am the source of the information.

During the course of an inquiry or investigation, the Radiation Protection Section will make its best effort to avoid actions that would clearly be expected to result in disclosure of my identity.

My identity may be divulged outside the Radiation Protection Section in the following situations:

- (1) When disclosure is necessary because of an overriding safety issue. The RPS staff will attempt to contact me prior to any disclosure.
- (2) When a court orders such disclosure.
- (3) When required by DHFS adjudicatory proceedings.
- (4) In response to a legislative request. While such a request will be handled on a case-by-case basis, RPS will make its best efforts to limit the disclosure to the extent possible.
- (5) When requested by a Federal or State agency in furtherance of its statutory responsibilities, and RPS finds that furtherance of the public interest requires such release.
- (6) When the Wisconsin Attorney General, the Office of Investigations (OI), the Department of Justice (DOJ), or a local or state law enforcement agency are pursuing an investigation, my identity may be disclosed without my knowledge or consent.
- (7) When I have taken actions that are inconsistent with and override the purpose of protecting my identity.

My identity will be withheld from RPS staff, except on a need-to-know basis. Consequently, I acknowledge that if I have further contacts with RPS personnel, I cannot expect that those people will be cognizant of my desire to remain anonymous, and it will be my responsibility to bring that point to their attention if I desire similar treatment for the information provided to them.

**Attachment 4.01-2  
Nondisclosure Statement-Example**

I have read and fully understand the information above.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Address

**Attachment 4.01-3  
Allegation Screening Form**

- a) Is there an immediate safety concern that must be quickly addressed?
- b) Is the allegation a specific safety or quality issue or a generalized concern?
- c) Has the staff previously addressed this issue or a similar issue?
- d) Have a substantial number of allegations on similar concerns been entered in the AMS?
- e) What is the time sensitivity of the allegation, and what immediate actions are necessary?
- f) What is the potential for wrongdoing and will investigative assistance be needed?
- g) Does the allegation package contain sufficient information for a thorough evaluation? If not, identify the additional information needed.
- h) Can the issues be adequately addressed by a routine technical inspection? If not, determine the best way to address the issues.
- i) Is the identity of the alleged necessary for a thorough evaluation?
- j) Identify any peripheral issues that could develop.
- k) Are any licensing actions or enforcement actions pending that could be affected by the allegation? When an allegation involves a case with pending licensing action, the nuclear engineer working on the case should be promptly notified.
- l) Can inspection resources be effectively utilized pursuing the issue or is the allegation too vague or frivolous?
- m) Is further consideration of the allegation required? If not, inform the alleged in a courteous and diplomatic manner of the rationale for not considering it further.
- n) Can licensee resources reasonably be used in resolving the allegation to conserve staff resources? See Section 3.4.
- o) Does the allegation have the potential to require escalated enforcement action?

**Attachment 4.01-4**  
**Confidential Information and Files**

Upon receipt of an allegation and during the investigation of an allegation, the allegor may request and reasonably expect that his/her identity will be protected as confidential information as long as an overriding safety issue has not been determined to exist. Basic rules to protect the identity of the allegor and other sensitive information are outlined below.

- 1) Restrict staff discussions to those individuals who truly need-to-know. The allegor's identity and other information that would reveal their identity should be withheld from other RPS staff not involved with the investigation.
- 2) Restrict access to the hardcopy and computer files by storing in a secure file in a locked room. All information regarding the allegor's identity will be stored in the specific Allegations File or computer file associated with the allegation. The Allegations File will be maintained in a locked filing cabinet. The Program Supervisors will control the key to the secure file. The computer file(s) will be password protected. When the workday is over, lock the room.
- 3) Protect access to hardcopy Allegation Files and computer files while you are working on them. Do not leave the file lying open on your desk if you leave your work area. Do not leave the word processing file on your computer screen if you leave your work area. At the end of the day, make sure the Allegations File is placed in the secure file. Save your word processing files on the secured computer space. Do not develop drafts outside this computer space.
- 4) Be wary of faxes and e-mails if you must utilize them. If you must fax something, be very careful to enter the correct telephone number. You should call prior to sending a fax and call to confirm the fax was received. Generally, it is not prudent to use e-mail to transmit confidential information. If you must use e-mail, consider discussing the issue(s) without including identifying information.
- 5) Ensure that reports and correspondence to other entities do not contain information that could lead to the identification of the allegor or confidential source. Other entities could include: the licensee, applicant, registrant, the Nuclear Regulatory Commission, other federal agency, or another Agreement State. If the RPS has chosen to refer the allegation to the licensee or registrant, do not include the original information submitted by the allegor. The information should be re-worded to reflect the basic facts and remove any language that could be used to identify the allegor.

Attachment 4.01-5  
**ACKNOWLEDGMENT LETTER TO ALLEGER**

[Alleger's Name]  
[Alleger's Address]

SUBJECT: Allegation No. [Number]

Dear [Alleger's Name]:

This letter refers to your [telephone conversation, meeting, interview etc.] with a member of the Radiation Protection Section (RPS) staff on [Date], in which you expressed concern related to [facility name]. You were concerned about [brief description of allegation].

Enclosure 1 to this letter documents your allegation as we understand it. The RPS has initiated actions to evaluate the allegation on the basis of the information that you have provided. If the description of your allegation in the enclosure is not accurate, please contact the RPS so that the information can be corrected.

In addition, according to your contact with RPS staff, we understand that you do not object to having your allegation referred to the [licensee, registrant] If, following initial evaluation, your allegation is referred to the [licensee, registrant], every reasonable effort will be made to protect your identity. These measures include the following:

- Your identity and information that would reveal your identity will be withheld from RPS staff except on a need-to-know basis,
- All information regarding the your identity will be stored in a secure file with controlled access,
- Inspection reports and correspondence to licensees, other Agreement States, Federal Agencies (including NRC), other organizations or individuals will contain no information that could lead to your identification, and
- Your identity or information regarding your identity will not be disclosed outside of RPS, except under the conditions stipulated below.

**Attachment 4.01-5**

**ACKNOWLEDGMENT LETTER TO ALLEGER**

Even though the above measures will be taken to protect your identity, the RPS cannot guarantee absolute confidentiality and disclosure of your identity may occur if:

- Disclosure is necessary because of an overriding safety issue,
- Disclosure is necessary pursuant to a legal order,
- Disclosure is necessary in furtherance of a wrongdoing investigation, including an investigation of a discrimination allegation,
- Disclosure is necessary to support a hearing on an enforcement matter, or
- You have taken actions that are inconsistent with and override the purpose of protecting the your identity.

RPS staff will inform you of the final disposition of your allegation. If you have any questions or further concerns, please contact me at (608) 266-XXXX.

Sincerely,

\_\_\_\_\_Program Supervisor

STATE OF WISCONSIN  
DEPARTMENT OF HEALTH AND FAMILY SERVICES  
RADIATION PROTECTION SECTION

Radioactive Materials Program Procedure No. 4.02  
Radiological Incident Response

Prepared By: Jason M. Hunt Date: 1-06-03  
Jason M. Hunt, Nuclear Engineer

Reviewed By: Cheryl K. Rogers Date: 1-06-03  
Cheryl K. Rogers, Materials Program Supervisor

Approved By: Paul S. Schmidt Date: 1-6-03  
Paul Schmidt, Radiation Protection Section Chief

Effective Date: 1-6-03

## Table of Contents

### 1.0 PURPOSE

#### 1.1 The following statements describe the applicability and purpose of this procedure. The procedure:

- 1.1.1 Applies to all Radiation Protection Section (RPS) staff responding to a non-nuclear power plant incident involving real or suspected radioactive materials. This procedure does not apply to a known or suspected terrorist incident. If terrorism is known or suspected, refer to Wisconsin Nuclear Incident Response Plan Appendix T.
- 1.1.2 Addresses preparations for responding to a radiological incident.
- 1.1.3 Describes appropriate radiation detection instruments and other equipment potentially required for use during a response to a radiological incident.
- 1.1.4 Describes safety precautions for RPS staff and other responders during a response effort.
- 1.1.5 Describes options for identifying unknown radioactive material in the field and laboratory.
- 1.1.6 Establishes guidelines for managing, including impounding, radioactive material that is, or could be, a threat to public health and safety.
- 1.1.7 Describes management options for radioactive material.

#### 1.2 References

- 1.2.1 Sections 254.31 to .45, WI Stats.
- 1.2.2 Chapter HFS 157 'Radiation Protection'

#### 1.3 Letters, Forms and Reports

- 1.3.1 Attachment 4.02-1 Incident Notification Form
- 1.3.2 Attachment 4.02-2 Radiological Incident Response Q&A

#### 1.4 Hardcopy Files

- 1.4.1 Wisconsin Incident File

## **1.5 Definitions**

## **2.0 RESPONSIBILITIES**

### **2.1 Program Assistant (PA)**

- Maintains the incident response reports, forms and analysis results in hard copy files.

### **2.2 Radiation Protection Section Staff (RPSS)**

- Notifies State Radiological Coordinator (SRC) upon initial receipt of notification of a radiological incident.
- Responds to incidents involving radioactive materials, as directed by supervisor.
- Assists SRC with incident response and documentation, including report preparation, as needed.

### **2.3 State Radiological Coordinator (SRC)**

- Receives initial notification of radiological incidents and determines level of response required.
- Informs Material Program Supervisor (MPS) of all radioactive material incidents.
- Coordinates assignment of staff to respond to incidents involving radioactive materials.
- Assumes the lead role in response to incidents involving radioactive materials and coordinates with the MPS.
- Participates on and coordinates any site team responding to a radiological incident.
- Prepares a report documenting the incident response, including all forms, surveys and analysis results.

### **2.4 Materials Program Supervisor (MPS)**

- Notifies RPS Chief of radiological incident.
- Assigns staff to respond to incidents involving radioactive materials.
- Coordinates response effort, in cooperation with the State Radiological Coordinator (SRC).
- Makes decisions based on SRC recommendations to impound radioactive materials found in the public domain with concurrence of the RPS Chief.
- May approve impoundment of radioactive materials in absence of RPS Chief.
- Recommends to the RPS Chief if legal assistance is required.
- Ensures that notifications are made of reportable events and required reports, as specified in HFS 157.13(17) & 157.32, to the NRC Operations Center and Region III Office for immediate and 24-hour reports, or the Region III Office for 30-day reports.

- Ensures that written documentation of reportable incidents is provided to the Region III office and NMED within 30 days of receipt of the report from licensee. Abnormal occurrences should be identified using the criteria in NUREG – 0090.

## 2.5 Radiation Protection Section Chief

- Final authority for radiological incident response activities (conflict resolution).
- Responsible for approving the impounding of radioactive materials discovered in the public domain or that threatens public health or safety.
- Requests legal assistance, if required.

## 3.0 PROCEDURE

### 3.1 Initial Notification

*Note: Direct all calls regarding radiological incidents to the SRC*

3.1.1 Obtain as much of the following information as possible from the caller:

- Caller's name, affiliation and location
- Phone number where caller may be reached.
- On-scene contact person and phone number.
- Location of the incident.
- Overall description of the incident, including any injuries.
- Indications that radioactive material is involved.
- Description of the radioactive material, including packaging.
- Any writing or inscriptions on the materials.
- Availability of a shipping manifest (transportation incident).
- Indications of a possible spread of contamination from meter readings, broken source housing, leaking packaging, etc.
- Other agencies or personnel involved.

3.1.2 Inform the Material Program Supervisor, or Section Chief if MPS is unavailable.

3.1.3 Determine the level of response required. Factors that should be considered include:

- Potential to escalate
- Location of incident
- Impact on routine public life or available services
- Potential for exposure or contamination
- Media interest
- Type of release
- Involvement of other responders

- Request for specific type of assistance
- 3.1.4 Advise the caller on proper measures to limit exposure and minimize the spread of contamination.

### 3.2 On Scene Response

3.2.1 A minimum of two people shall respond to a radiological incident.

3.2.2 All equipment necessary to respond to a radioactive materials incident is located in Rm B371 or Rm 144/150. The following equipment shall be obtained and transported to the incident scene:

- A 'response kit' that contains pre-selected supplies (See Attachment 4.02-3 Response Kit Inventory).
- A minimum of two GM contamination survey instruments equipped with 'pancake' type detectors.
- One low range exposure rate hand-held instrument.
- One higher range exposure rate hand-held instrument.

*Note: Prior to use, all instruments shall be battery and source checked and have a current calibration. Log out all instruments removed from storage room on form provided.*

- A multi-channel analyzer if the situation may require a field identification of unknown isotopes.
- Personally assigned dosimetry and a direct reading dosimeter.
- Camera
- Cellular phone.
- Other instruments and supplies, as necessary.

*Note: Each state field team possesses a calibrated contamination survey meter and a dose rate meter.*

### 3.2.3 Site Approach

- Approach the incident site/material from upwind.
- Turn on exposure rate instrument before approaching the incident site.
- Obtain current information from on scene personnel.
- Coordinate response efforts prior to approaching the material.
- Ask for a shipping manifest if a transportation incident.
- If there is the potential for contamination, wear plastic booties and gloves.
- Establish a 2 mR/hr exclusion zone around the material if not already done. Determine who may enter the exclusion zone and under what conditions.

3.2.4 Document the following, as it occurs, in the notebook provided in the 'response kit':

- Date and time of all major activities related to the incident.
- Model and serial numbers of all instruments used.
- Calibration date of all instruments used.
- Names of RPS responders.
- A physical description of the incident site.
- Location or orientation of any materials.
- Background radiation levels.
- Survey results.
- Amount of material present.
- Any markings or inscriptions associated with the material.
- Disposition of the material.
- Names, phone numbers and addresses of all individuals involved, in case follow-up is required.

3.2.5 Determine if material needs packaging.

*Note: If material must be bagged, double bag the material with a minimum of one MIL-SPEC yellow bag being the outermost bag. Seal bags with tape. Attach a completed radioactive-material tag to the outside bag, including activity, isotopes and radiation readings.*

3.2.6 After the material has been safely packaged or ensured to be in safe condition, do the following:

- Determine best location for temporary storage.
- Ensure that decontamination issues are addressed.
- Initiate attempt to locate owner of material.
- Contact Materials Program Supervisor (primary) or RPS Section Chief (secondary) for direction and authorization for management of the material (See Attachment 4.02-4 Radiological Incident Response Impoundment Guidelines).

*Note: Attachment 4.02-3 specifies radioactive material impoundment guidelines.*

- If the material is verified as NRC controlled material, notify via the 24-hour NRC Operations Center (301-816-5100).
- If no owner can be found, notify EPA (312-886-5026 during normal business hours or 312-353-2318 during off-hours) for possible assistance in disposing of the material, if appropriate.

3.2.7 Materials being transported for analysis or storage should be packaged to meet DOT requirements, if practical.

*Note: DOT exemptions should be used for scrap and waste shipments containing unidentified radioactive material.*

### **3.3 Report**

- 3.3.1 The SRC shall prepare a draft report within 15 days documenting all information gathered, the disposition of the material and a list of all the parties involved. The report is required for all incident response, including phone consultation for reportable incidents. The draft report shall be in memo form and addressed to the Materials Program Supervisor. After MPS review and concurrence, the final report shall be issued within 15 days.
- 3.3.2 Provide a copy of the final report to the Chief, Radiation Protection Section.
- 3.3.3 Provide a copy of the report, analysis results and all notes and related paperwork to the Program Assistant, Materials Program for filing.
- 3.3.4 If required by Materials Program Supervisor, input incident data to the Nuclear Material Events Database (NMED) and forward event reports to the NRC. For additional guidance on forwarding reports to the NRC for inclusion in the NMED, refer to STP Procedure SA-300 and Handbook entitled "Nuclear Materials Event Reporting in Agreement States."

### **3.4 Follow-up**

- 3.4.1 Replace all inventoried supplies used in the 'response kit' from the inventory supply located in B371 storage room.
- 3.4.2 Return all instruments to storage room and log in on form provided.
- 3.4.3 In consultation with Materials Program Supervisor, determine if any whole body counts, bioassays or personnel dose determinations are warranted.
- 3.4.4 In consultation with Materials Program Supervisor, determine if training or information for any individuals involved in the incident is warranted.

## **4.0 RECORDS**

### **4.1 Hardcopy**

- 4.1.1 Incident Notification Form
- 4.1.2 Notebook provided in "Response Kit"
- 4.1.3 Report on Incident

## **4.2 Computer Based**

- 4.2.1 NMED Report – If applicable
- 4.2.2 Local Incident Report – WI Database

## **5.0 ATTACHMENTS TO RMPP No. 4.02**

### **5.1 Attachments**

- 5.1.1 Attachment 4.02-1 Radiological Incident Notification Form
- 5.1.2 Attachment 4.02-2 Radiological Incident Response Q&A
- 5.1.3 Attachment 4.02-3 “Response Kit” Inventory
- 5.1.4 Attachment 4.02-4 Impoundment Guidelines

# Radiological Incident Notification Form

## Contact Information

SRC's Name \_\_\_\_\_

Date and Time of Notification \_\_\_\_\_ / \_\_\_\_\_  
Date Time

Incident Reported By:

On-site Contact

Name:

Name:

Title/Organization:

Title/Organization:

Phone Number:

Phone Number:

## Location of Incident (DIRECTIONS)

## Description of Incident

## Radiation Assessment

1. Why do you believe radioactive material is involved?

2. Describe the radioactive material including packaging.

3. Did you observe any writing or inscriptions on the materials?

4. Are the shipping papers available?

5. Are there any indications of a possible spread of contamination based on meter readings, broken source housing, leaking packaging, etc.

6. Has the source or contaminated area been isolated or access to the area restricted?

7. What other agencies or personnel are involved?

## **Radiological Incident Response Impoundment Guidelines**

Management will consider the following questions before approving a request to impound radioactive materials:

### **Regulatory Control:**

- Are the radioactive materials under the direct control and responsibility of a licensee or registrant?
- Are the materials in a controlled location?
- Are the materials directly and negatively impacting public health and safety?
- Is there a possible public perception problem with the current location?

### **Physical/chemical form:**

- What is the isotope and physical/chemical form of the material?
- Are other hazardous or explosive materials involved?
- What is activity of the material?

### **Physical condition:**

- Are the materials intact, crushed, leaking or damaged in some way?
- Are the materials concentrated or dispersed over a large area?
- Are the materials separate or part of a larger device?

**Amount:** What is the volume of the material?

**Transportation:** Can the materials be transported safely?

### **Waste management:**

Does managing the materials involve simple storage or is any processing involved in disposing of the materials?

### **Alternatives:**

- Are there any safe and reasonable alternatives to the state impounding the material?
- Is there a temporary storage location and responsible party available?

RESPONSE KIT INVENTORY

- 10 pairs of rubber gloves and cotton liners
- 1 box of disposable rubber gloves
- 2 rolls of duct tape
- 1 roll of rad tape
- 10 4.5 x 9 ziplock bags
- 10 12 x 16 ziplock bags
- 6 small yellow mil-spec poly bags
- 3 large yellow mil-spec poly bags
- 3 tyvek coveralls
- 10 pairs of disposable booties
- pens and markers
- 2 long tweezers
- 1 small tweezer
- wipes
- 2 cans of rad-con spray
- 1 roll of paper towels
- 1 emergency response guidebook
- 1 notebook
- 1 clipboard and paper
- 10 radioactive material tags
- 4 rad signs
- 50 feet approximately of magenta and yellow rope
- 1 knife
- 1 procedure book

## **Radiological Incident Response Question and Answer Sheet**

### **What is a radiological incident?**

A radiological incident is an emergency involving radioactive materials. Examples of radiological incidents include situations where radioactive materials are lost, stolen or involved in a transportation accident. In most cases, radiological incidents can be successfully resolved by emergency responders with state assistance.

### **What state assistance is available to respond to a radiological incident?**

The Department of Health and Family Services, Radiation Protection Section (RPS), is available on a 24-hour basis to support and advise emergency responders during an incident involving radioactive materials. RPS emergency response resources include highly trained personnel, specialized radiation monitoring equipment and a mobile radiological laboratory. RPS staff can be quickly dispatched to provide on-site assistance at the scene of a radiological incident.

### **How are radioactive materials regulated to minimize public risk?**

Radioactive materials are stringently regulated by state and federal government agencies by licensing or registration. Devices and products containing radioactive materials are required to incorporate safety features that minimize the exposure risk to the public from a radiological incident.

### **What should I do if involved in a radiological incident?**

Remain calm. Follow instructions given by on-scene officials. State of Wisconsin, Radiation Protection Section staff will quickly assess the situation and recommend any further actions. Most radiological incidents do not result in harmful levels of radiation exposure to the public.

### **Where can I get more information?**

For more information on radiological incident response or health risk from exposure to radiation or radioactive materials, contact:

Paul Schmidt  
Nuclear Engineer Manager  
Radiation Protection Section  
(608) 267-4792  
[schmips@dhfs.state.wi.us](mailto:schmips@dhfs.state.wi.us)