

INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS



Date: November 10, 2006

Mr. Darrel Wiedeman
US Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Mr. Wiedeman,

RADIATION
SAFETY OFFICE

Here are the completed forms you had faxed to us. As a note, our office has made some additional notations and comments due to the ambiguity of many of the questions. If you have any questions, please contact our office. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Mason", with a long horizontal flourish extending to the right.

Jeff Mason, Assistant RSO
IUPUI/IU Medical Center

Clinical Building 159
541 Clinical Drive
Indianapolis, Indiana
46202-5111

317-274-4797
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*IU School of Medicine
IU Medical Center &
Associated Facilities*

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Attachment A

INFORMATION COLLECTION INTERVIEW OUTLINE

Inspector's name and Region: Darrel Wiedeman

Date of inspection: 10/16-20/2006

A. General facility information

1. Facility name/location: IUPUI/Indiana University Medical Center
Riley Childrens Hospital ← Nuclear Medicine
2. License number: 13-02752
3. Docket number: 030-01609
4. Number of beds: 250
5. Estimated number of procedures administered annually:
 - ~~400~~ ⁵³⁰ Inpatient diagnostic
 - ~~1600~~ Outpatient diagnostic
 - 0 Inpatient therapeutic (radiopharmaceutical)
 - 15 Outpatient therapeutic (radiopharmaceutical)
 - 0 Inpatient manual brachytherapy (35.400 and 35.1000)
 - 0 Outpatient manual brachytherapy (35.400 and 35.1000)

6. Top 5 common diagnostic and therapeutic procedures involving unsealed byproduct material or implants containing byproduct material at this facility:

Diagnostic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. Genitourinary	900	2-10 mCi	75%
2. Gastrointestinal	650	0.5-5 mCi	75
3. Musculoskeletal	325	5-25 mCi	75
4. Cardiovascular	70	5-30 mCi	90
5. Thyroid	45	0.2-2 mCi	100%

Therapeutic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. Thyroid	15	10-20 mCi	100%
2.			
3.			
4.			
5.			

B. General information on individual interviewed

1. Name: Cheryl Shiplett
2. Title/Position: team leader
3. Years of experience: 26
4. Years of experience in this facility: 19
5. In which of the following step(s) of byproduct material administration are you involved?

- Informing individuals that they will be receiving unsealed byproduct material or implants containing byproduct material
- Making a decision on when an individual can be released from the facility
- Communicating risk and safety information to individual

C. Procedure for individuals with detectable amounts of radioactivity who may activate monitors installed in public locations for increased security

1. Are you familiar with the NRC Information Notice issued on December 9, 2003 entitled "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" and voluntary actions recommended in this notice?

- Yes
- No

2. Are the individuals administered therapeutic radiopharmaceuticals or manual brachytherapy implants informed that they may activate radiation detectors at airports, tunnels, and other public places?

- Not applicable
- Yes
- Why not?

3. Are the individuals administered diagnostic radiopharmaceuticals informed that they may activate radiation detectors at airports, tunnels, and other public places?

- Not applicable
- Yes
- No. Why not?

4. Does your facility provide documents to individuals to use if they are questioned by law enforcement or security personnel?

- Yes. What types of documents are provided? *Please provide us with a copy*
- No. Is your facility prepared to offer such documents on request?

- Yes
- No

5. How can law enforcement or security personnel verify that an individual has received a procedure involving byproduct material in your facility?

- By calling a telephone number we provided to the individual
- Will not be able to verify
- Other. Please explain.

By calling Riley Nuclear Medicine

(Pt. is given instruction form for use following therapy. Physician's name is on this form.)

6. If your facility provides a card or documentation for the individual to carry, who is the facility contact listed on the documentation? (provide no names please, just position or title)

7. Is this contact available at all times?

- Yes
- No

8. What procedures are in place in your facility to ensure that the contact person listed can get access to updated information related to the individual who carries the documentation?

9. In your experience, has your facility ever been contacted because somebody activated a radiation detector?

- No
- Yes. Please describe how your facility responded.

10. In your experience, are the current procedures regarding released individuals who can activate radiation detectors adequate?

- Yes
- No. What changes would you recommend?

D. Informed consent

1. How are individuals informed that they will receive unsealed byproduct material or an implant containing byproduct material?

Discussion with technologist, physician.

2. When are individuals informed? (e.g., at registration, immediately before administration)

Prior to procedure

3. Who informs them?

Technologist / physician

E. Making a decision on release of individuals from your facility

For each of the questions, please specify if the answer for iodine administrations is the same or different than for other radionuclides.

1. How do you determine when an individual who received byproduct material or implants containing byproduct material can be released from your facility?

- By using default values (specify source)
- Based on administered activity
- Based on dose rate measured from patient
- Dose calculations using patient-specific parameters
- Other (specify)

Please explain how each applicable category is used. Only address methods used at your facility.

Physician completes form.

2. Do you make this decision alone or in collaboration with others?

- Alone
- With others. Please explain respective roles

Physician

3. When is the determination on the timing of release made?

- Before administration of radiopharmaceutical or implant
- After administration of radiopharmaceutical or implant

4. If an individual indicates that they cannot meet release criteria (e.g. must take public transportation or cannot have sole use of bathroom) what additional information is collected to support release?

5. Based on your experience, please estimate what percent of patients indicate that they cannot meet at least one of the release criteria:

_____ %

Please indicate the most frequent release criteria for which concerns are raised:

- Maintaining distance from other persons, including separate sleeping arrangements
- Minimizing time in public places (e.g. using public transportation, shopping, visiting restaurants, etc)
- Taking procedures to reduce the spread of contamination (e.g. sole use of bathroom)
- Minimizing time with children and pregnant women

(siblings)

6. Have there been any changes/revisions to the procedures of releasing individuals in the past five years?

- No
- Yes. Please describe the changes.

7. In your view, are the current facility procedures adequate?

- Yes
- No. What changes would you recommend?

F. Providing instructions to individuals upon release from your facility on actions recommended for maintaining doses to other individuals as low as is reasonably achievable

Please provide us with copies of all materials

1. Do you use specific guidelines in making a decision on what types of instructions are provided to individuals?

- No
- Yes. Please explain

Therapy pts. have a discussion with the nuclear med. physician and receive instruction form the day prior

2. If the total effective dose equivalent to any other individual is likely to exceed to therapy 1 mSv (0.1 rem), the individual released from your facility receives:

- Both oral and written instructions
- Written instructions only
- Oral instructions only
- No specific instructions

3. If the total effective dose equivalent to any other individual is NOT likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:

- Both oral and written instructions
- Written instructions only
- Oral instructions only
- No specific instructions

4. Do the instructions differ depending on the radionuclide?

- No
- Yes. Please elaborate.

5. When are the instructions provided?

Before the procedure
 After the procedure
 Either before or after

Therapy pts. receive written instructions the day prior to therapy and the day of therapy. Oral discussion is with technologist the day prior to therapy and with MS the day of therapy.

6. Which of the following may influence the type of instructions given to the released individual? Please explain.

Individual breast-feeds an infant
 Individual cares for an infant/young child but does NOT breast-feed

N/A

7. If the released individual needs constant care from a caregiver at home, are instructions provided for the caregiver?

Yes
 No

8. If an individual asks questions or expresses concerns about unsealed byproduct materials or implants, is additional information or counseling offered?

No
 Yes. Who provides the information/counseling?

technologist or physician

9. Based on your experience, please estimate what percent of individuals express concerns related to radiation or radioactivity and/or request additional information?

Individuals never express concerns or request information
 10%
 10-30%
 30-50%
 50-70%
 70%

10. Have you received any training in patient education/counseling?

Yes. Please elaborate

*Note: The hospital does not
conduct, but the
RSO has an
Annual Inservice*

No. Would you consider such training beneficial?

Yes

No

*for
not*

11. Have there been any changes/revisions to patient communication procedures or instructional materials in your facility in the past five years?

No

Yes. Please elaborate

12. In your experience, are the current patient communication procedures adequate?

Yes

No. What changes would you recommend?

13. Is it possible for an individual administered therapeutic radiopharmaceuticals or manual brachytherapy implants to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No

Yes. Please give examples how this might happen.

14. Is it possible for an individual administered diagnostic radiopharmaceuticals to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No

Yes. Please give examples how this might happen.

**PLEASE REMEMBER TO PROVIDE COPIES OF ALL
EDUCATIONAL/SAFETY INSTRUCTIONS AS WELL AS MATERIALS FOR
PRESENTATION AT SECURITY CHECKPOINTS.
THANK YOU!**

Issue Date: 10/13/06

A1-10

2800/039, Attachment 1

Attachment A

INFORMATION COLLECTION INTERVIEW OUTLINE

Inspector's name and Region: Darrel Wiedeman

Date of inspection: 10/16-20/2006

A. General facility information

1. Facility name/location: **Indiana University School of Medicine
Radiation Oncology ←**

2. License number: **13-02752-08**

3. Docket number: **030-09792**

4. Number of beds:

5. Estimated number of procedures administered annually:

- Inpatient diagnostic
- Outpatient diagnostic
- Inpatient therapeutic (radiopharmaceutical)
- 210 Outpatient therapeutic (radiopharmaceutical)
- 400 Inpatient manual brachytherapy (35.400 and 35.1000)
- 210 Outpatient manual brachytherapy (35.400 and 35.1000)

6. Top 5 common diagnostic and therapeutic procedures involving unsealed byproduct material or implants containing byproduct material at this facility:

Diagnostic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1.			
2.			
3.			
4.			
5.			

N/A

Therapeutic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. Cs-137 GYNE	50	50-200	0
2. P-32	25	15	100
3. I-125	25	25-50	100
4. Pd-103	25	25-50	100
5. Au-198	25	30-60 mCi	100
6. Ir-192	110	30-200 mCi	0

B. General information on individual interviewed

1. Name: COLLEEN DESROSIERS
2. Title/Position: MEDICAL PHYSICIST
3. Years of experience: 18
4. Years of experience in this facility: 10
5. In which of the following step(s) of byproduct material administration are you involved?
 - Informing individuals that they will be receiving unsealed byproduct material or implants containing byproduct material
 - Making a decision on when an individual can be released from the facility
 - Communicating risk and safety information to individual

C. Procedure for individuals with detectable amounts of radioactivity who may activate monitors installed in public locations for increased security

1. Are you familiar with the NRC Information Notice issued on December 9, 2003 entitled "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" and voluntary actions recommended in this notice?
 - Yes
 - No

2. Are the individuals administered therapeutic radiopharmaceuticals or manual brachytherapy implants informed that they may activate radiation detectors at airports, tunnels, and other public places?

- Not applicable
 Yes
 Why not?

3. Are the individuals administered diagnostic radiopharmaceuticals informed that they may activate radiation detectors at airports, tunnels, and other public places?

- Not applicable
 Yes
 No. Why not?

4. Does your facility provide documents to individuals to use if they are questioned by law enforcement or security personnel?

- Yes. What types of documents are provided? *Please provide us with a copy INSTRUCTIONS FOR PATIENT AND CAREGIVER*
 No. Is your facility prepared to offer such documents on request?

- Yes
 No

5. How can law enforcement or security personnel verify that an individual has received a procedure involving byproduct material in your facility?

- By calling a telephone number we provided to the individual
 Will not be able to verify
 Other. Please explain.

6. If your facility provides a card or documentation for the individual to carry, who is the facility contact listed on the documentation? (provide no names please, just position or title)

RADIATION ONCOLOGY DEPT, RADIATION SAFETY OFFICE

7. Is this contact available at all times?
AFTER HOURS, RADIATION ONCOLOGY RESIDENT ON CALL

Yes

No

8. What procedures are in place in your facility to ensure that the contact person listed can get access to updated information related to the individual who carries the documentation?

THE RADIATION ONCOLOGY RESIDENT HAS ACCESS

TO THE PATIENT'S RADIATION ONCOLOGY CHART

9. In your experience, has your facility ever been contacted because somebody activated a radiation detector?

No

Yes. Please describe how your facility responded.

10. In your experience, are the current procedures regarding released individuals who can activate radiation detectors adequate?

Yes

No. What changes would you recommend?

NONE OF THE FORMS IN RADIATION ONCOLOGY MENTION SETTING OFF DETECTORS / IS IT NECESSARY FOR P-32, I-125, Pd-103?

I WOULD NOT EXPECT THAT THESE ISOTOPES WOULD SET OFF

D. Informed consent

DETECTORS

1. How are individuals informed that they will receive unsealed byproduct material or an implant containing byproduct material?

BY THEIR PHYSICIAN, THE PATIENTS SIGN CONSENT FOR TREATMENT

2. When are individuals informed? (e.g., at registration, immediately before administration)

VARIES

3. Who informs them?

PHYSICIAN / RESIDENT PHYSICIAN

E. Making a decision on release of individuals from your facility

For each of the questions, please specify if the answer for iodine administrations is the same or different than for other radionuclides.

1. How do you determine when an individual who received byproduct material or implants containing byproduct material can be released from your facility?

- By using default values (specify source)
- Based on administered activity
- Based on dose rate measured from patient
- Dose calculations using patient-specific parameters
- Other (specify)

Please explain how each applicable category is used. Only address methods used at your facility.

see attached table

2. Do you make this decision alone or in collaboration with others?

- Alone
- With others. Please explain respective roles

PER TABLE (?)

3. When is the determination on the timing of release made?

- Before administration of radiopharmaceutical or implant
- After administration of radiopharmaceutical or implant

4. If an individual indicates that they cannot meet release criteria (e.g. must take public transportation or cannot have sole use of bathroom) what additional information is collected to support release?

N/A

5. Based on your experience, please estimate what percent of patients indicate that they cannot meet at least one of the release criteria:

N/A %

Please indicate the most frequent release criteria for which concerns are raised:

- Maintaining distance from other persons, including separate sleeping arrangements
 - Minimizing time in public places (e.g. using public transportation, shopping, visiting restaurants, etc)
 - Taking procedures to reduce the spread of contamination (e.g. sole use of bathroom)
 - Minimizing time with children and pregnant women
6. Have there been any changes/revisions to the procedures of releasing individuals in the past five years?
- No
 - Yes. Please describe the changes.

7. In your view, are the current facility procedures adequate?

- Yes
- No. What changes would you recommend?

F. Providing instructions to individuals upon release from your facility on actions recommended for maintaining doses to other individuals as low as is reasonably achievable

Please provide us with copies of all materials

1. Do you use specific guidelines in making a decision on what types of instructions are provided to individuals?
 - No
 - Yes. Please explain

2. If the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:
 - Both oral and written instructions
 - Written instructions only
 - Oral instructions only
 - No specific instructions

3. If the total effective dose equivalent to any other individual is NOT likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:
 - Both oral and written instructions
 - Written instructions only
 - Oral instructions only
 - No specific instructions

4. Do the instructions differ depending on the radionuclide?
 - No
 - Yes. Please elaborate.

SEPARATED VS UNSEPARATED SOURCES

5. When are the instructions provided?

- Before the procedure
- After the procedure
- Either before or after

6. Which of the following may influence the type of instructions given to the released individual? Please explain.

- Individual breast-feeds an infant
- Individual cares for an infant/young child but does NOT breast-feed

EXTENDED CLOSE CONTACT IS NOT RECOMMENDED / BRIEF CONTACT
OK - HUGS / KISSES

7. If the released individual needs constant care from a caregiver at home, are instructions provided for the caregiver?

- Yes, IF CAREGIVER AVAILABLE
- No

8. If an individual asks questions or expresses concerns about unsealed byproduct materials or implants, is additional information or counseling offered?

- No
- Yes. Who provides the information/counseling?
PHYSICIST, PHYSICIAN, RSO AS APPLICABLE

9. Based on your experience, please estimate what percent of individuals express concerns related to radiation or radioactivity and/or request additional information?

- Individuals never express concerns or request information
- 10% (<10%)
- 10-30%
- 30-50%
- 50-70%
- 70%

10. Have you received any training in patient education/counseling?

Yes. Please elaborate

*I.U. conducts
in-services for
rad users*

*AT THE INSTITUTION WHERE I PREVIOUSLY WORKED,
SEMINARS WERE ROUTINELY GIVEN. I ATTENDED 2 SEMINARS*

No. Would you consider such training beneficial?

Yes

No

11. Have there been any changes/revisions to patient communication procedures or instructional materials in your facility in the past five years?

No

Yes. Please elaborate

12. In your experience, are the current patient communication procedures adequate?

Yes

No. What changes would you recommend?

13. Is it possible for an individual administered therapeutic radiopharmaceuticals or manual brachytherapy implants to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No

Yes. Please give examples how this might happen.

14. Is it possible for an individual administered diagnostic radiopharmaceuticals to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

N/A

- No
 Yes. Please give examples how this might happen.

**PLEASE REMEMBER TO PROVIDE COPIES OF ALL
EDUCATIONAL/SAFETY INSTRUCTIONS AS WELL AS MATERIALS FOR
PRESENTATION AT SECURITY CHECKPOINTS.
THANK YOU!**



PERMANENT IMPLANT DOSE RATE SURVEY FORM

Patient Name: _____

MRN: _____

IMPLANT INFORMATION:

Radionuclide Used: ¹²⁵I ¹⁰³Pd ¹⁹⁸Au

Activity Implanted (mCi): _____ Date & Time of Implant: _____

Dose Rate Measurement at 1 meter: _____ mR/hr

NOTE: Permanent implant patients may be released if they meet the following criteria:

- ¹⁰³Pd total activity is ≤ 40 mCi or the dose rate at 1 meter is ≤ 3 mR/hr.
- ¹⁹⁸Au total activity is ≤ 93 mCi or the dose rate at 1 meter is ≤ 21 mR/hr.
- ¹²⁵I total activity is ≤ 9 mCi or the dose rate at 1 meter is ≤ 1 mR/hr.

Use the dose rate at 1 meter and the table below to determine the length of time patients should follow the special instructions indicated in Section B of the *Home Guidelines for Patients Receiving Permanent Radiation Implants* form.

103Pd (mCi)	103Pd (mR/hr)	125I (mCi)	125I (mR/hr)	198Au (mCi)	198Au (mR/hr)
2.5 - 3.0	6 days	17 - 21	6 days	0.9 - 1	130 days
2.0 - 2.4	5 days	13 - 16	5 days	0.8 - 0.9	120 days
1.5 - 1.9	4 days	10 - 12	4 days	0.7 - 0.8	120 days
1.0 - 1.4	3 days	8 - 9	3 days	0.6 - 0.7	103 days
0.7 - .9	2 days	6 - 7	2 days	0.5 - 0.6	95 days
< 0.7	1 day	4 - 5	1 day	0.4 - 0.5	77 days
		< 4	0 days	0.3 - 0.4	50 days
				0.2 - 0.3	35 days
				< 0.2	0 days

Please circle time indicated on the guidelines provided to the patient.

ROOM SURVEY:

Room Number: _____

Radiation levels at or below background: YES NO

If the radiation levels are not at or below background please give explanation or describe the corrective action taken to rectify the situation:

OTHER INFORMATION:

Instructions provided to the patient? YES NO

Surveyor: _____ Date: _____

Instrument Used: Victoreen 450B #1548 Victoreen 470A #104138
 Ludlum 3 ** Other: _____

**Enter A for Ludlum 3 S/N 111720. B for S/N 128506. C for S/N 193935. D for S/N 211854. E for S/N 212006

Attachment A

INFORMATION COLLECTION INTERVIEW OUTLINE

Inspector's name and Region: Darrel Wiedeman
 Date of inspection: 10/16-20/2006

A. General facility information

1. Facility name/location: IUPUI/Indiana University Medical Center
 Wishard Memorial Hospital ←
2. License number: 13-02752
3. Docket number: 030-01609
4. Number of beds: 275
5. Estimated number of procedures administered annually:

- 840 Inpatient diagnostic
- 1769 Outpatient diagnostic
- 3 Inpatient therapeutic (radiopharmaceutical)
- 72 Outpatient therapeutic (radiopharmaceutical)
- 0 Inpatient manual brachytherapy (35.400 and 35.1000)
- 0 Outpatient manual brachytherapy (35.400 and 35.1000)

6. Top 5 common diagnostic and therapeutic procedures involving unsealed byproduct material or implants containing byproduct material at this facility:

Diagnostic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. MYOCARDIAL Perfusion	1105	10 - 35 mCi	72%
2. BONE	415	20 - 30 mCi	70%
3. Thyroid Uptake/scan	212	0.4 mCi	97%
4. WBC Scan	179	0.3 - 0.6 mCi	42%
5. LUNGS	132	4 - 6 mCi	18%

Therapeutic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. Hyperthyroid	65	15-20	99%
2. Thyroid CA	10	100	100%
3.			
4.			
5.			

B. General information on individual interviewed

1. Name: *Monica Clift*
2. Title/Position: *Supervisor Nuclear Medicine*
3. Years of experience: *27*
4. Years of experience in this facility: *4*
5. In which of the following step(s) of byproduct material administration are you involved?
 - Informing individuals that they will be receiving unsealed byproduct material or implants containing byproduct material
 - Making a decision on when an individual can be released from the facility
 - Communicating risk and safety information to individual

C. Procedure for individuals with detectable amounts of radioactivity who may activate monitors installed in public locations for increased security

1. Are you familiar with the NRC Information Notice issued on December 9, 2003 entitled "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" and voluntary actions recommended in this notice?
 - Yes
 - No

2. Are the individuals administered therapeutic radiopharmaceuticals or manual brachytherapy implants informed that they may activate radiation detectors at airports, tunnels, and other public places?

Not applicable

Yes

Why not?

Never encountered that type of problem

3. Are the individuals administered diagnostic radiopharmaceuticals informed that they may activate radiation detectors at airports, tunnels, and other public places?

Not applicable

Yes

No. Why not?

Never encountered that type of problem

4. Does your facility provide documents to individuals to use if they are questioned by law enforcement or security personnel?

Yes. What types of documents are provided? *Please provide us with a copy*

No. Is your facility prepared to offer such documents on request?

Yes

No

5. How can law enforcement or security personnel verify that an individual has received a procedure involving byproduct material in your facility?

By calling a telephone number we provided to the individual

Will not be able to verify

Other. Please explain.

6. If your facility provides a card or documentation for the individual to carry, who is the facility contact listed on the documentation? (provide no names please, just position or title)

Do Not Provide a Card

7. Is this contact available at all times?

- Yes
 No

8. What procedures are in place in your facility to ensure that the contact person listed can get access to updated information related to the individual who carries the documentation?

9. In your experience, has your facility ever been contacted because somebody activated a radiation detector?

- No
 Yes. Please describe how your facility responded.

10. In your experience, are the current procedures regarding released individuals who can activate radiation detectors adequate?

- Yes
 No. What changes would you recommend?

D. Informed consent

1. How are individuals informed that they will receive unsealed byproduct material or an implant containing byproduct material?

*Physicians and or Technologists
Orally*

- 2. When are individuals informed? (e.g., at registration, immediately before administration)

Before procedure

- 3. Who informs them?

Physician and/or Technologist

E. Making a decision on release of individuals from your facility

For each of the questions, please specify if the answer for iodine administrations is the same or different than for other radionuclides.

- 1. How do you determine when an individual who received byproduct material or implants containing byproduct material can be released from your facility?

- By using default values (specify source)
- Based on administered activity
- Based on dose rate measured from patient
- Dose calculations using patient-specific parameters
- Other (specify)

Please explain how each applicable category is used. Only address methods used at your facility.

Use Questionnaire form

- 2. Do you make this decision alone or in collaboration with others?

- Alone
- With others. Please explain respective roles

- 3. When is the determination on the timing of release made?

- Before administration of radiopharmaceutical or implant
- After administration of radiopharmaceutical or implant

4. If an individual indicates that they cannot meet release criteria (e.g. must take public transportation or cannot have sole use of bathroom) what additional information is collected to support release?

Give them additional time to be able to meet the criteria

5. Based on your experience, please estimate what percent of patients indicate that they cannot meet at least one of the release criteria:

5 %

Please indicate the most frequent release criteria for which concerns are raised:

- Maintaining distance from other persons, including separate sleeping arrangements
 - Minimizing time in public places (e.g. using public transportation, shopping, visiting restaurants, etc)
 - Taking procedures to reduce the spread of contamination (e.g. sole use of bathroom)
 - Minimizing time with children and pregnant women
6. Have there been any changes/revisions to the procedures of releasing individuals in the past five years?
- No
 - Yes. Please describe the changes.

7. In your view, are the current facility procedures adequate?

- Yes
- No. What changes would you recommend?

F. Providing instructions to individuals upon release from your facility on actions recommended for maintaining doses to other individuals as low as is reasonably achievable

Please provide us with copies of all materials

1. Do you use specific guidelines in making a decision on what types of instructions are provided to individuals?
 - No
 - Yes. Please explain

2. If the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:
 - Both oral and written instructions
 - Written instructions only
 - Oral instructions only
 - No specific instructions

3. If the total effective dose equivalent to any other individual is NOT likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:
 - Both oral and written instructions
 - Written instructions only
 - Oral instructions only
 - No specific instructions

4. Do the instructions differ depending on the radionuclide?
 - No
 - Yes. Please elaborate.

5. When are the instructions provided?

- Before the procedure
- After the procedure
- Either before or after

6. Which of the following may influence the type of instructions given to the released individual? Please explain.

- Individual breast-feeds an infant *instruct not to breastfeed for a time period.*
- Individual cares for an infant/young child but does NOT breast-feed

7. If the released individual needs constant care from a caregiver at home, are instructions provided for the caregiver?

- Yes *Universal Precautions Time / Distance*
- No

8. If an individual asks questions or expresses concerns about unsealed byproduct materials or implants, is additional information or counseling offered?

- No
- Yes. Who provides the information/counseling?
Physician

9. Based on your experience, please estimate what percent of individuals express concerns related to radiation or radioactivity and/or request additional information?

- Individuals never express concerns or request information
- 10% less than
- 10-30%
- 30-50%
- 50-70%
- 70%

10. Have you received any training in patient education/counseling?

Note! The hospital does not conduct, but the RSO has an annual inservice for licensed

Yes. Please elaborate

No. Would you consider such training beneficial?

Yes

No

11. Have there been any changes/revisions to patient communication procedures or instructional materials in your facility in the past five years?

No

Yes. Please elaborate

12. In your experience, are the current patient communication procedures adequate?

Yes

No. What changes would you recommend?

13. Is it possible for an individual administered therapeutic radiopharmaceuticals or manual brachytherapy implants to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No

Yes. Please give examples how this might happen.

- 14. Is it possible for an individual administered diagnostic radiopharmaceuticals to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No

Yes. Please give examples how this might happen.

**PLEASE REMEMBER TO PROVIDE COPIES OF ALL
EDUCATIONAL/SAFETY INSTRUCTIONS AS WELL AS MATERIALS FOR
PRESENTATION AT SECURITY CHECKPOINTS.
THANK YOU!**

Attachment A

INFORMATION COLLECTION INTERVIEW OUTLINE

Inspector's name and Region: **Darrel Wiedeman**
 Date of inspection: **10/16-20/2006**

A. General facility information

1. Facility name/location: **IUPUI/Indiana University Medical Center
Indiana University Hospital ←**
2. License number: **13-02752**
3. Docket number: **030-01609**
4. Number of beds: **330**
5. Estimated number of procedures administered annually: **Sept YTD 2007**

- 389 Inpatient diagnostic
- 1179 Outpatient diagnostic
- 0 Inpatient therapeutic (radiopharmaceutical)
- 78 Outpatient therapeutic (radiopharmaceutical)
- _____ Inpatient manual brachytherapy (35.400 and 35.1000)
- _____ Outpatient manual brachytherapy (35.400 and 35.1000)

6. Top 5 common diagnostic and therapeutic procedures involving unsealed byproduct material or implants containing byproduct material at this facility:

Diagnostic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. Bone	433	20-30	83%
2. Cardiac gated	158	30	78%
3. Lymph nodes	107	1-3	89%
4. Thyroids	72	.3-1	99%
5. Thy CA+CB	65	1-3	100%

Therapeutic Procedures	Estimated number of procedures performed annually	Range of radioactivity administered (mCi) per individual	Percentage treated as outpatient
1. Therapy-Oral	75		100%
2. Therapy-IV	2		100%
3. Therapy-Infusion mAb	1		100%
4.			
5.			

B. General information on individual interviewed

1. Name: **DAWN BURKHARDT**
2. Title/Position: **TEAM LEAD**
3. Years of experience: **15**
4. Years of experience in this facility: **15**
5. In which of the following step(s) of byproduct material administration are you involved?
 - Informing individuals that they will be receiving unsealed byproduct material or implants containing byproduct material
 - Making a decision on when an individual can be released from the facility
 - Communicating risk and safety information to individual

C. Procedure for individuals with detectable amounts of radioactivity who may activate monitors installed in public locations for increased security

1. Are you familiar with the NRC Information Notice issued on December 9, 2003 entitled "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" and voluntary actions recommended in this notice?
 - Yes
 - No

2. Are the individuals administered therapeutic radiopharmaceuticals or manual brachytherapy implants informed that they may activate radiation detectors at airports, tunnels, and other public places?

- Not applicable
- Yes
- Why not?

3. Are the individuals administered diagnostic radiopharmaceuticals informed that they may activate radiation detectors at airports, tunnels, and other public places?

- Not applicable
- Yes
- No. Why not?

BECAUSE A PROCEDURE HAS NOT BEEN IMPLEMENTED AT THIS TIME.

4. Does your facility provide documents to individuals to use if they are questioned by law enforcement or security personnel?

- Yes. What types of documents are provided? *Please provide us with a copy*
- No. Is your facility prepared to offer such documents on request?

- Yes
- No

5. How can law enforcement or security personnel verify that an individual has received a procedure involving byproduct material in your facility?

- By calling a telephone number we provided to the individual
- Will not be able to verify
- Other. Please explain.

COULD CALL HOSPITAL + WE COULD VERIFY

6. If your facility provides a card or documentation for the individual to carry, who is the facility contact listed on the documentation? (provide no names please, just position or title)

N/A

7. Is this contact available at all times?

- Yes
- No

8. What procedures are in place in your facility to ensure that the contact person listed can get access to updated information related to the individual who carries the documentation?

9. In your experience, has your facility ever been contacted because somebody activated a radiation detector?

- No
- Yes. Please describe how your facility responded.

10. In your experience, are the current procedures regarding released individuals who can activate radiation detectors adequate?

- Yes
- No. What changes would you recommend?

D. Informed consent

1. How are individuals informed that they will receive unsealed byproduct material or an implant containing byproduct material?

FOR THERAPY? THEN YES

2. When are individuals informed? (e.g., at registration, immediately before administration) **BEFORE ADMINISTRATION**

3. Who informs them? **DR.**

E. Making a decision on release of individuals from your facility

For each of the questions, please specify if the answer for iodine administrations is the same or different than for other radionuclides.

- 1. How do you determine when an individual who received byproduct material or implants containing byproduct material can be released from your facility?
 - By using default values (specify source)
 - Based on administered activity
 - Based on dose rate measured from patient
 - Dose calculations using patient-specific parameters
 - Other (specify)

Please explain how each applicable category is used. Only address methods used at your facility.

- 2. Do you make this decision alone or in collaboration with others?
 - Alone
 - With others. Please explain respective roles
THE DR. MAKES THIS DECISION

- 3. When is the determination on the timing of release made?
 - Before administration of radiopharmaceutical or implant
 - After administration of radiopharmaceutical or implant

- 4. If an individual indicates that they cannot meet release criteria (e.g. must take public transportation or cannot have sole use of bathroom) what additional information is collected to support release?

ANYTHING THAT IS DIRECTLY RELATED TO THEIR SITUATION

- 5. Based on your experience, please estimate what percent of patients indicate that they cannot meet at least one of the release criteria:

5 %

Please indicate the most frequent release criteria for which concerns are raised:

- Maintaining distance from other persons, including separate sleeping arrangements
- Minimizing time in public places (e.g. using public transportation, shopping, visiting restaurants, etc)
- Taking procedures to reduce the spread of contamination (e.g. sole use of bathroom)
- Minimizing time with children and pregnant women

- 6. Have there been any changes/revisions to the procedures of releasing individuals in the past five years?

- No
- Yes. Please describe the changes.

- 7. In your view, are the current facility procedures adequate?

- Yes
- No. What changes would you recommend?

F. Providing instructions to individuals upon release from your facility on actions recommended for maintaining doses to other individuals as low as is reasonably achievable

Please provide us with copies of all materials

1. Do you use specific guidelines in making a decision on what types of instructions are provided to individuals?

- No
- Yes. Please explain

2. If the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:

- Both oral and written instructions
- Written instructions only
- Oral instructions only
- No specific instructions

3. If the total effective dose equivalent to any other individual is NOT likely to exceed 1 mSv (0.1 rem), the individual released from your facility receives:

- Both oral and written instructions
- Written instructions only
- Oral instructions only
- No specific instructions

4. Do the instructions differ depending on the radionuclide?

- No
- Yes. Please elaborate.

ONLY GIVE INSTRUCTIONS FOR ¹³¹I

5. When are the instructions provided?

- Before the procedure
- After the procedure
- Either before or after

6. Which of the following may influence the type of instructions given to the released individual? Please explain.

- Individual breast-feeds an infant
- Individual cares for an infant/young child but does NOT breast-feed

BOTH - WILL HAVE TO STOP BREASTFEEDING
+ LIMIT TIME IF IBI

7. If the released individual needs constant care from a caregiver at home, are instructions provided for the caregiver?

- Yes
- No

8. If an individual asks questions or expresses concerns about unsealed byproduct materials or implants, is additional information or counseling offered?

- No
- Yes. Who provides the information/counseling?

DR OR RADIATION SAFETY

9. Based on your experience, please estimate what percent of individuals express concerns related to radiation or radioactivity and/or request additional information?

- Individuals never express concerns or request information
- 10%
- 10-30%
- 30-50%
- 50-70%
- 70%

10. Have you received any training in patient education/counseling?

Yes. Please elaborate

Note: The hospital does not, but the RSO conducts an annual inservice

No. Would you consider such training beneficial?

Yes

No

11. Have there been any changes/revisions to patient communication procedures or instructional materials in your facility in the past five years?

No

Yes. Please elaborate

ALWAYS CHANGING TO BE MORE INFORMATIVE

12. In your experience, are the current patient communication procedures adequate?

Yes

No. What changes would you recommend?

13. Is it possible for an individual administered therapeutic radiopharmaceuticals or manual brachytherapy implants to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No

Yes. Please give examples how this might happen.

14. Is it possible for an individual administered diagnostic radiopharmaceuticals to leave your facility without the knowledge that they emit detectable levels of radiation remaining from their procedure?

No *both*

Yes. Please give examples how this might happen.

*NOT EVERYONE UNDERSTANDS
WHAT A RADIOISOTOPE IS.*

**PLEASE REMEMBER TO PROVIDE COPIES OF ALL
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PRESENTATION AT SECURITY CHECKPOINTS.
THANK YOU!**

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