# Appendix S:

# Model Procedure for Return of Radioactive Wastes from Customers

# Model Procedure for Return of Radioactive Wastes from Customers

## Procedures for Customers to Return Radioactive Waste to The Radiopharmacy

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with DOT requirements (49 CFR 173.421). For those packages containing radioactive material in excess of the limited quantity, customers should ensure that all applicable DOT requirements are met for the packages. This includes, but is not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, please follow your in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as excepted package of limited quantity:

- Ensure that the activities of material being returned are limited quantities as defined by DOT (see table below). Special attention should be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.
- Place the syringe or vial in the original, labeled, lead shield in which it was delivered; and
- Place shielded waste into the shipping package (e.g., padded briefcase or ammo box) in which it was delivered.

*Note:* Packages used to ship radioactive material to customers must meet the DOT package requirements for transport of limited quantities.

Preparation of package:

- Using a calibrated survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/hr;
- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed the limit specified in 49 CFR 173.443(a), 22 dpm/$cm^2$ over a 300 $cm^2$ area;
- Label the package as a "Excepted Package - Limited Quantity of Material"; and
- Seal the package so that it will be evident upon receipt whether the package accidentally opened during shipment.

*Note:* Shipping papers are not required when shipping limited quantities however, the statement specified in 49 CFR 173.422 ("This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910.") must be included in, on, or otherwise provided with the shipment.

**Limited Quantities (49 CFR 173.421) For Typical Radionuclides as Liquid Used by Radiopharmacies (49 CFR 173.425 - Table 7)**

**Table 7. Limited Quantity Values for Liquid Radioactive Material Packages**

| Radionuclide – Liquids | A2 Value | Limited Quantity Shipment (mCi) A2 X $10^{-4}$ |
|---|---|---|
| Co-57 | 216 | 21.6 |
| Co-58 | 27 | 2.7 |
| Cr-51 | 811 | 81.1 |
| Ga-67 | 162 | 16.2 |
| I-123 | 162 | 16.2 |
| I-125 | 54.1 | 5.41 |
| I-131 | 13.5 | 1.35 |
| In-111 | 54.1 | 5.41 |
| Mo-99 | 20 (for domestic use) | 2 |
| P-32 | 8.11 | 0.81 |
| Se-75 | 81.1 | 8.1 |
| Sr-89 | 13.5 | 1.35 |
| Tc-99m | 216 | 21.6 |
| Tl-201 | 270 | 27 |

**Table 8. Limited Quantity Values for Gaseous Radioactive Material Packages**

| Radionuclide Uncompressed Gas | A2 Value (Ci) | Limited Quantity Shipment (mCi) A2 X $10^{-3}$ |
|---|---|---|
| Xe-133 (uncompressed) | 541 | 541 |

**Table 9. Limited Quantity Values for Special Form Radioactive Material Packages**

| Radionuclide Solid – Special Form | A1 Value (Ci) | Limited Quantity Shipment (mCi) A1 X $10^{-3}$ |
|---|---|---|
| Ir-192 | 27 | 27 |
| Cs-137 | 54.1 | 54.1 |

The values above are derived from 49 CFR 173.423, Table 7, and the Table of A1 and A2 values for radionuclides in 49 CFR 173.435. If shipping more than one radionuclide in the same package, the limits in 173.433(d) apply as follows: The sum of the ratios of the activity of each radionuclide divided by its respective A2 value must be less than, or equal to, one. For special form material, the sum of the ratios of the activities of each radionuclide divided by its respective A1 value must be less than, or equal to, one.

## Procedure for Driver or Courier for Pick-up of Radioactive Waste from Customers

- Ensure that the shipping package is properly labeled "Excepted Package - Limited Quantity of Material";
- Ensure that the shipping package has been sealed; and
- Do not accept any package that is not properly labeled and sealed.

## Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste

- Place all returned packages in an identifiable location within the radiopharmacy;
- Put on disposable gloves;
- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than 22 dpm/cm$^2$ over a 300 cm$^2$ area, take the following actions:
  - ✓ Notify the customer and the department; and
- Survey the driver/courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy.
  - ✓ Decontaminate the package or remove it from service for decay.

Open the package and identify each nuclide in the shielded containers.

Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.

Survey the dose shields for contamination with a low-level survey meter. Any dose shield that indicate activity exceeding background should be decontaminated or removed from service.

# Appendix T:

# *DHFS* Incident Notifications

## *DHFS* Incident Notifications

**Table 10. Typical Notifications Required for Radiopharmacy Licensees**

| Event | Telephone Notification | Written Report | Regulatory Requirement |
|---|---|---|---|
| Theft or loss of material | Immediate | 30 days | *HFS 157.32(1)* |
| Whole body dose greater than 0.25 Sv (25 rems) | Immediate | 30 days | *HFS 157.32(2)* |
| Extremity dose greater than 2.5 Sv (250 rems) | Immediate | 30 days | *HFS 157.32(2)* |
| Intake of five times the annual limit on intake | Immediate | 30 days | *HFS 157.32(2)* |
| Removable contamination exceeding the limits of *HFS 157.94(1)* – [beta/gamma/low toxicity alpha – 22 dpm/cm$^2$; all other alpha – 2.2 dpm/cm$^2$] | Immediate | 30 days | *HFS 157.29(6)* |
| External radiation levels exceeding the limits of *10 CFR 71.47* – [any point on the surface – 2 mSv/hr (200 mrem/hr)] | Immediate | None | *HFS 157.29(6)* |
| Whole body dose greater than 0.05 Sv (5 rems) in 24 hours | 24 hours | 30 days | *HFS 157.32(2)* |
| Extremity dose greater than 0.5 Sv (50 rems) in 24 hours | 24 hours | 30 days | *HFS 157.32(2)* |
| Intake one annual limit on intake | 24 hours | 30 days | *HFS 157.32(2)* |
| Occupational dose greater than the applicable limit in *HFS 157.22(1)* | None | 30 days | *HFS 157.32(3)* |
| Dose to individual member of public greater than 1 mSv (100 mrems) | None | 30 days | *HFS 157.32(3)* |
| Filing petition for bankruptcy under 11 U.S.C. | None | Immediately after filing petition | *HFS 157.13 (9)(b) and (10)* |

| Event | Telephone Notification | Written Report | Regulatory Requirement |
|---|---|---|---|
| Expiration of license | None | 60 days | *HFS 157.13(11)* |
| Decision to permanently cease licensed activities at ***entire site*** | None | 60 days | *HFS 157.13(11)* |
| Decision to permanently cease licensed activities in any ***separate building or outdoor area*** that is unsuitable for release for unrestricted use | None | 60 days | *HFS 157.13(11)* |
| No principal activities conducted for 24 months ***at the entire site*** | None | 60 days | *HFS 157.13(11)* |
| Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits | Immediate | 30 days | *HFS 157.13(17)* |
| An unplanned contamination event involving greater than 5 times the ALI, and half-life greater than 24 hours requiring access to be restricted for more than 24 hours | 24 hours | 30 days | *HFS 157.13(17)* |
| Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits | 24 hours | 30 days | *HFS 157.13(17)* |
| Unplanned fire or explosion that affects the integrity of any radioactive material or device, container, or equipment with radioactive material | 24 hours | 30 days | *HFS 157.13(17)* |

*Note:* Telephone notifications shall be made to ***DHFS*** at **(608) 267-4797** (office hours) and in an emergency to **(608) 258-0099** (after hours).

# Appendix U:

# Reserved

# Authorized User and Radiation Safety Officer Experiences in Handling Radioisotopes

**(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)**

| Name (Last, First, Initial) |
|---|

| Isotope(s) Used | Maximum amount Used at any one time | Location of Use | Purpose of Use* | Total Hours of Experience |
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*** Purpose of Use**

1. **Shipping, receiving, and performing related radiation surveys**
2. **Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides**
3. **Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides**
4. **Calculating, assaying, and safely preparing radioactive materials**
5. **Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures**

# Authorized Nuclear Pharmacist
# Experiences in Handling Radioisotopes

**(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)**

| Name (Last, First, Initial) |
|---|

| Isotope(s) Used | Maximum amount Used at any one time | Location of Use | Purpose of Use* | Total Hours of Experience |
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| **Signature of Preceptor Authorized Nuclear Pharmacist:** "I certify that the above training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a Nuclear Pharmacy." | **Signature:** | **Date:** |
|---|---|---|

*** Purpose of Use**

1. **Shipping, receiving, and performing related radiation surveys**
2. **Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high energy beta-emitting radionuclides**
3. **Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta- emitting radionuclides**
4. **Calculating, assaying, and safely preparing radioactive materials**
5. **Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures**

# Authorized Nuclear Pharmacist
# Training in Basic Radioisotope Handling Techniques

**Name** (Last, First, Initial)

| Location of Training | Dates | Title | Total Hours | Breakdown of Course in Clock Hours | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | RPP | BH | IR | INST | REG |
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| | | | Totals | | | | | |

| Signature of Preceptor Authorized Nuclear Pharmacist: "I certify that the above described training/experience has been satisfactory completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy." | Signature: | Date: |
|---|---|---|

**RPP** Radiation Protection Principles

**IR** Ionizing Radiation Units & Characteristics

**REG** *DHFS* Rule and Standards

**BH** Biological Hazards

**INST** Radiation Detection Instrumentation

# Authorized User or Radiation Safety Officer
# Training in Basic Radioisotope Handling Techniques

| Name (Last, First, Initial) |
|---|
| |

| Location of Training | Dates | Title | Total Hours | Breakdown of Course in Clock Hours | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | RPP | BH | IR | INST | REG |
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| | | | Totals | | | | | |

RPP Radiation Protection Principles

IR Ionizing Radiation Units & Characteristics

REG *DHFS* Rule and Standards

BH Biological Hazards

INST Radiation Detection Instrumentation

# *Wisconsin Administrative Code*

# *Chapter HFS 157 - Radiation Protection*

# *Regulatory Guide*
## *(WISREG 8.29)*

Revision 0 – August 2002

# Risks from Occupational Radiation Exposure

**Department of Health and Family Services**
**Division of Public Health**
**Radiation Protection Section**
**P.O Box 2659**
**Madison, WI 53701-2659**
**Phone: (608) 267-4797**
**Fax: (608) 267-3695**

**PPH 45028 (08/02)**

## INTRODUCTION

Wisconsin Administrative Code HFS 157.88(2), "Instructions to Workers", requires that all individuals who in the course of employment are likely to receive an occupational radiation dose in excess of one mSv (100 millirem) in a year be instructed in health protection issues associated with exposure to radioactive materials or radiation. HFS 157.22(6), "Planned Special Exposures", requires that before a planned special exposure occurs the individual involved are, among other things, to be informed of the estimated doses and associated potential risks.

This Wisconsin Regulatory Guide (WISREG 8.29) describes the information that should be provided to workers by licensees or registrants about health risks from occupational exposure.

Any information collection activities mentioned in this regulatory guide are contained as requirements in Chapter HFS 157 "Radiation Protection". These rules provide the regulatory basis for this guide.

## DISCUSSION

It is important to qualify the material presented in this guide with the following considerations.

The coefficient used in this guide for occupational radiation risk estimates, $4 \times 10^4$ health effects per rem, is based on data obtained at much higher doses and dose rates than those encountered by workers. The risk coefficient obtained at high doses and dose rates was reduced to account for the reduced effectiveness of lower doses and dose rates in producing the stochastic effects observed in studies of exposed humans. The assumption of a linear extrapolation from the lowest doses at which effects are observable down to the occupational range has considerable uncertainty. The report of the Committee on the Biological Effects of Ionizing Radiation (Reference 1, page 4) states that

> *"departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the 100 mrem dose range. Thus, the possibility that there may be no risk from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero. "*

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (Reference. 2) addresses the issue of beneficial effects from low doses, or hormesis, in cellular systems. UNSCEAR states that *" it would be premature to conclude that cellular adaptive responses could convey possible beneficial effects to the organism that would outweigh the detrimental effects of exposures to low doses of low-LET radiation. "*

In the absence of scientific certainty regarding the relationship between low doses and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation can cause biological effects that may be harmful to the exposed person and that the magnitude or probability of these effects is directly proportional to the dose. These effects may be classified into three categories:

> **Somatic Effects**: Physical effects occurring in the exposed person. These effects may be observable after a large or acute dose (e. g., 100 rem (***Note:*** *In the International System of Units (SI), the rem is replaced by the sievert; 100 rem is equal to 1 sievert (1 Sv) or more to the*

*whole body in a few hours*); or there may be effects such as cancer that may occur years after exposure to radiation.

**Genetic Effects***:* Abnormalities that may occur in the future children of exposed individuals and in subsequent generations (genetic effects exceeding normal incidence have not been observed in any of the studies of human populations).

**Teratogenic Effects***:* Effects such as cancer or congenital malformation that may be observed in children who were exposed during the fetal and embryonic stages of development (these effects have been observed from high, i.e., above 0.2 Sv (20 rem) acute exposures.

The normal incidence of effects from natural and manmade causes is significant. For example, approximately 20% of people die from various forms of cancer whether or not they ever receive occupational exposure to radiation. To avoid increasing the incidence of such biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for workers who are occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with Wisconsin Administrative Code HFS 157. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training and should generate more interest on the part of the workers in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have available to them relevant information on radiation risks to enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop respect for the risks involved, rather than excessive fear or indifference.

## REGULATORY POSITION

Instruction to workers performed in compliance with HFS 157.88(2) should be given prior to occupational exposure and annually thereafter. If a worker is to participate in a planned special exposure, the worker should be informed of the associated risks in compliance with HFS 157.22(6).

In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation. The extent of these instructions should be commensurate with the radiological risks present in the workplace. The instruction should be presented orally, in printed form, or in any other effective communication media to workers and supervisors. The appendix to this guide provides useful information for demonstrating compliance with the training requirements in HFS 157. Individuals should be given an opportunity to discuss the information and to ask questions. Testing is recommended, and each trainee should be asked to acknowledge in writing that the instruction has been received and understood.

## IMPLEMENTATION

The purpose of this section is to provide information to applicants, licensees and registrants regarding the use of this regulatory guide. Except in those cases in which an applicant, licensee, or registrant proposes acceptable alternative methods for complying with specified portions of the HFS 157, the guidance and instructional materials in this guide will be used in the evaluation of applications for new licenses, registrations,

license renewals, and license amendments and for evaluating compliance with HFS 157.88(2) and HFS 157.22.

## REFERENCES

1. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation,* Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.

2. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), Sources *and Effects of Ionizing Radiation,* United Nations, New York, 1993.

## APPENDIX

## INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the radiation worker with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta and alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when they deposit energy in living tissue. A question and answer format is used. The Nuclear Regulatory Commission (NRC) developed many of the questions and answers.

The information in this appendix is intended to help develop respect by workers for the risks associated with radiation, rather than unjustified fear or lack of concern. Additional guidance concerning other topics in radiation protection training is provided in other DHFS regulatory guides and NRC regulatory guides.

### 1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action in terms of whether we believe that particular action will, or will not, cause us some harm. The intent of this appendix is to provide estimates of, and explain the bases for, the risk of injury, illness, or death from occupational radiation exposure. Risk can be quantified in terms of the probability of a health effect per unit of dose received.

When x-rays, gamma rays, and ionizing particles interact with living materials such as our bodies, they may deposit enough energy to cause biological damage. Radiation can cause several different types of events such as the very small physical displacement of molecules, changing a molecule to a different form, or ionization, which is the removal of electrons from atoms and molecules. When the quantity of radiation energy deposited in living tissue is high enough, biological damage can occur as a result of chemical bonds being broken and cells being damaged or killed. These effects can result in observable clinical symptoms.

The basic unit for measuring absorbed radiation is the rad. 0.01 Gy (One rad) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of material such as tissue exposed to radiation. To reflect biological risk, rads must be converted to rem. The new international unit is the sievert (100 rem = 1 Sv). This conversion accounts for the differences in the effectiveness of different types of radiation in causing damage. The rem is used to estimate biological risk. For beta and gamma radiation, a rem is considered equal to a rad.

### 1. What are the possible health effects of exposure to radiation?

Health effects from exposure to radiation range from no effect at all to death, including diseases such as leukemia or bone, breast, and lung cancer. Very high (10's of Gy or 100s of rads), short-term doses of radiation have been known to cause prompt (or early) effects, such as vomiting and diarrhea, (Note: These symptoms are early indicators of what is referred to as the acute radiation syndrome, caused by high doses delivered over a short time period, which includes damage to the blood- forming organs such as bone marrow, damage to the gastrointestinal system, and, at very high doses, can include damage to the central nervous system) skin burns, cataract and even death. It is suspected that radiation exposure may be linked to the potential for genetic effects in the children of exposed parents. Also, children who were exposed to high doses (20 mGy or 20 or more rads) of radiation prior to birth (as an embryo/fetus) have shown an increased risk of mental retardation and other congenital malformations. These effects (with the exception of genetic effects) have been observed in various studies of medical radiologists, uranium miners, radium workers, radiotherapy

patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, radiation effects studies with laboratory animals, in which the animals were given relatively high doses, have provided extensive data on radiation-induced health effects, including genetic effects.

It is important to note that these kinds of health effects result from high doses, compared to occupational levels, delivered over a relatively short period of time.

Although studies have not shown a consistent cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent from a worker protection perspective to assume that some effects may occur.

**3. What is meant by early effects and delayed or late effects?**

**EARLY EFFECTS**

Early effects, which are also called immediate or prompt effects, are those that occur shortly after a large exposure that is delivered within hours to a few days. They are observable after receiving a very large dose in a short period of time, for example, 3 Gy (300 rads) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under HFS 157 occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells so that large numbers of cells are killed. For early effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not cause the same effect. The body's natural biological processes are constantly repairing damaged cells and replacing dead cells; if the cell damage is spread over time, the body is capable of repairing or replacing some of the damaged cells, reducing the observable adverse conditions.

For example, a dose to the whole body of about 3-5 Gy (300-500 rads), more than 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death if medical treatment is not provided. These effects would not occur if the same dose were accumulated gradually over many weeks or months (References 1 and 2, page 22). Thus, one of the justifications for establishing annual dose limits is to ensure that occupational dose is spread out over time.

It is important to distinguish between whole body and partial body exposure. A localized dose to a small volume of the body would not produce the same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to the skin and underlying tissue of the hand. An acute dose of 4-6 Gy (400 to 600 rads) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death; however, it would not totally eliminate the effects or the chance of death.

**DELAYED EFFECTS**

Delayed effects may occur years after exposure. These effects are caused indirectly when the radiation changes parts of the cells in the body, which causes the normal function of the cell to change, for example, normal healthy cells turn into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits on occupational doses.

A delayed effect of special interest is genetic effects. Genetic effects may occur if there is radiation damage to the cells of the gonads (sperm or eggs). These effects may show up as genetic defects in the children of the exposed individual and succeeding generations. However, if any genetic effects (i.e., effects in addition to the normal expected number) have been caused by radiation, the numbers are too small to have been observed in human populations exposed to radiation. For example, the atomic bomb survivors (from Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Reference 3, page 22). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. However, it is believed that by maintaining worker exposures below the HFS 157 limits and consistent with ALARA, a margin of safety is provided such that the risk of genetic effects is almost eliminated.

**4. What is the difference between acute and chronic radiation dose?**

Acute radiation dose usually refers to a large dose of radiation received in a short period of time. Chronic dose refers to the sum of small doses received repeatedly over long time periods, for example, 0.2 mSv (20 mrem) per week every week for several years. It is assumed for radiation protection purposes that any radiation dose, either acute or chronic, may cause delayed effects. However, only large acute doses cause early effects; chronic doses within the occupational dose limits do not cause early effects. Since the HFS 157 limits do not permit large acute doses, concern with occupational radiation risk is primarily focused on controlling chronic exposure for which possible delayed effects, such as cancer, are of concern.

The difference between acute and chronic radiation exposure can be shown by using exposure to the sun's rays as an example. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin, however, repeated short exposures provide time for the skin to be repaired between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer,

Cataracts are an interesting case because they can be caused by both acute and chronic radiation. A certain threshold level of dose to the lens of the eye is required before there is any observable visual impairment, and the impairment remains after the exposure is stopped. The threshold for cataract development from acute exposure is an acute dose on the order of 1 Gy (100 rads). Further, a cumulative dose of 8 Gy (800 rads) from protracted exposures over many years to the lens of the eye has been linked to some level of visual impairment (References 1 and 4, page 22). These doses exceed the amount that may be accumulated by the lens from normal occupational exposure under the current regulations.

**5. What is meant by external and internal exposure?**

A worker's occupational dose may be caused by exposure to radiation that originates outside the body, called "external exposure", or by exposure to radiation from radioactive material that has been taken into the body, called "internal exposure". Most HFS 157 licensed or registered activities involve little, if any, internal exposure. It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. HFS 157 requires that doses from external and internal exposure be added together, if each exceeds 10% of the annual limit, and that the total be within occupational limits. The sum of external and internal dose is called the total effective dose equivalent (TEDE) and is expressed in units of Sv (rem).

Although unlikely, radioactive materials may enter the body through breathing, eating, drinking, or open wounds, or they may be absorbed through the skin. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the

workplace atmosphere. The surfaces of equipment and workbenches may be contaminated, and these materials can be resuspended in air during work activities.

If any radioactive material enters the body, the material goes to various organs or is excreted, depending on the biochemistry of the material. Most radioisotopes are excreted from the body in a few days. For example, a fraction of any uranium taken into the body will deposit in the bones, where it remains for a longer time. Uranium is slowly eliminated from the body, mostly by way of the kidneys. Most workers are not exposed to uranium. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, an annual limit on intake (ALI) has been established for each radionuclide. When more than one radionuclide is involved, the intake amount of each radionuclide is reduced proportionally. HFS 157 Appendix E specifies the concentrations of radioactive material in the air to which a worker may be exposed for 2,000 working hours in a year. These concentrations are termed the derived air concentrations (DACs). These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources (from breathing air at 1 DAC) is the maximum allowed to an organ or to the worker's whole body.

### 6. How does radiation cause cancer?

The mechanisms of radiation-induced cancer are not completely understood. When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves and permanent damage is not caused. The cells can die, much like the large numbers of cells that die every day in our bodies, and be replaced through the normal biological processes. Or a change can occur in the cell's reproductive structure, the cells can mutate and subsequently be repaired without effect, or they can form pre-cancerous cells, which may become cancerous. Radiation is only one of many agents with the potential for causing cancer, and cancer caused by radiation cannot be distinguished from cancer attributable to any other cause.

Radiobiologists have studied the relationship between large doses of radiation and cancer (References 5 and 6, page 22). These studies indicate that damage or change to genes in the cell nucleus is the main cause of radiation-induced cancer. This damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through the actions of chemical products produced by radiation interactions within cells. Cells are able to repair most damage within hours; however, some cells may not be repaired properly. Such misrepaired damage is thought to be the origin of cancer, but misrepair does not always cause cancer. Some cell changes are benign or the cell may die; these changes do not lead to cancer.

Many factors such as age, general health, inherited traits, sex, as well as exposure to other cancer-causing agents such as cigarette smoke can affect susceptibility to the cancer-causing effects of radiation. Many diseases are caused by the interaction of several factors, and these interactions appear to increase the susceptibility to cancer.

### 7. Who developed radiation risk estimates?

Radiation risk estimates were developed by several national and international scientific organizations over the last 45 years. These organizations include the National Academy of Sciences (which has issued several reports from the Committee on the Biological Effects of Ionizing Radiation, BEIR), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombing at Hiroshima and Nagasaki. For example, UNSCEAR

published risk estimates in 1988 and 1993 (References 5 and 6, page 22). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates" (Reference 7, page 22). In January 1990, the National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Reference 4, page 22). Each of these publications also provides extensive bibliographies on other published studies concerning radiation health effects for those who may wish to read further on this subject.

**8. What-are the estimates of the risk of fatal cancer from radiation exposure?**

We don't know exactly what the chances are of getting cancer from a low-level radiation dose, primarily because the few effects that may occur cannot be distinguished from normally occurring cancers. However, we can make estimates based on extrapolation from extensive knowledge from scientific research on high dose effects. The estimates of radiation effects at high doses are better known than are those of most chemical carcinogens (Reference 8, page 22).

From currently available data, DHFS has adopted a risk value for an occupational dose of 1 rem (0.01 Sv) Total Effective Dose Equivalent (TEDE) of 4 in 10,000 of developing a fatal cancer or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates.

The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 0.05 Sv (5 rem) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Only a very few workers receive doses near 0.05 Sv (5 rem) per year (Reference 9, page 22).

According to the BEIR V report (Reference 4, page 22), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 (20%) will die from cancer without any occupational radiation exposure.

To explain the significance of these estimates, we will use as an example a group of 10,000 people, each exposed to 0.01 Sv (1 rem) of ionizing radiation. Using the risk factor of 4 effects per 100 Sv (10,000 rem) of dose, we estimate that 4 of the 10,000 people might die from delayed cancer because of that 0.01 Sv (l-rem) dose (although the actual number could be more or less than 4) in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. This means that a 0.01 Sv (l-rem) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 0.1Sv (10 rem), we could raise the estimate to 20.4 percent. A lifetime dose of 1 Sv (100 rem) may increase chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers reported to the NRC was 31. mSv (0.31 rem) for 1993 (Ref. 9). Today, very few workers ever accumulate 1 Sv (100 rem) in a working lifetime, and the average career dose of workers at NRC licensed facilities is 0.015 Sv (1.5 rem), which represents an estimated increase from 20 to about 20.06 percent in the risk of dying from cancer.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck of cards, will you get the ace of spades?" This question cannot be answered with a simple yes or no. The best answer is that your chance is 1 in 52. However, if 1,000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have 1 chance in 52 of drawing the ace of spades, but there is no way we can predict which person will get that card. The issue is further complicated by the fact that in a drawing by 1,000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have

increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who have not received any occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 0.01 Sv (1 rem) is about the same as the chance of drawing any ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 0.1 Sv (10 rem) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates based on data for people and research animals exposed to high levels of radiation in short periods of time. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer.

These estimates are considered by the DHFS to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

**9. If I receive a radiation dose that is within occupational limits, will it cause me to get cancer?**

Probably not, based on the risk estimates previously discussed, the risk of cancer from doses below the occupational limits is believed to be small. Assessment of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 0.1 Sv (10 rem) (Reference 3, page 22). For radiation protection purposes, these estimates are made using the straight-line portion of the linear quadratic model (Curve 2 in Figure 1, page 9). We have data on cancer probabilities only for high doses, as shown by the solid line in Figure 1. Only in studies involving radiation doses above occupational limits are there dependable determinations of the risk of cancer, primarily because below the limits the effect is small compared to differences in the normal cancer incidence from year to year and place to place. The ICRP, NCRP, and other standards-setting organizations assume for radiation protection purposes that there is some risk, no matter how small the dose (Curves 1 and 2). Some scientists believe that the risk drops off to zero at some low dose (Curve 3), the threshold effect, The ICRP and NCRP endorse the linear quadratic model as a conservative means of assuring safety (Curve 2); For regulatory purposes, DHFS uses the straight line portion of Curve 2, which shows the number of effects decreasing linearly as the dose decreases. Because the scientific evidence does not conclusively demonstrate whether there is or is not an effect at low doses, DHFS assumes for radiation protection purposes, that even small doses have some chance of causing cancer. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are manmade, such as cigarette smoke, smog, and x-rays.

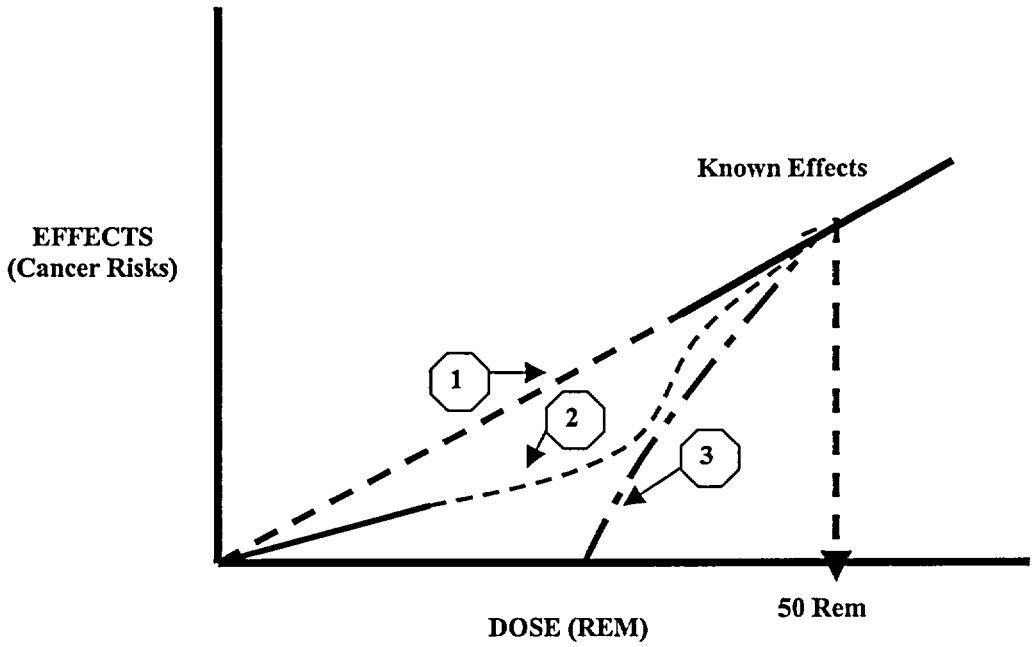


**Figure 1.** ***Some Proposed Models for How the Effects of Radiation Vary With Doses at Low Levels***

**10. How can we compare the risk of cancer from radiation to other kinds of health risks?**

One way to make these comparisons is to compare the average number of days of life expectancy lost because of the effects associated with each particular health risk. Estimates are calculated by looking at a large number of persons, recording the age when death occurs from specific causes, and estimating the average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total observed group.

Several studies have compared the average days of life lost from exposure to radiation with the number of days lost as a result of being exposed to other health risks. The word "average" is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers do not suffer any loss.

Some representative numbers are presented in Table 1 (page 12). For categories of NRC-regulated industries with larger doses, the average measurable occupational dose in 1993 was 3.1 mSv (0.31 rem). A simple calculation based on the article by Cohen and Lee (Reference 10, page 22) shows that 3 mSv (0.3 rem) per year from age 18 to 65 results in an average loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we encounter and accept in normal day-to-day activities.

It is also useful to compare the estimated average number of days of life lost from occupational exposure to radiation with the number of days lost as a result of working in several types of industries. Table 2 (page 13) shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include non-accident types of occupational risks such as occupational disease and stress because the data is not available.

These comparisons are not ideal because we are comparing the possible effects of chronic exposure to radiation to different kinds of risk such as accidental death, in which death is inevitable, if the event occurs. This is the best we can do because good data is not available on chronic exposure to other workplace carcinogens. Also, the estimates of loss of life expectancy for workers from radiation-induced cancer do not take into consideration the competing effect on the life expectancy of the workers from industrial accidents.

**Table 1**
**Estimated Loss of Life Expectancy from Health Risks [a]**

| Health Risk | Estimate of Life Expectancy Lost (Average) | |
|---|---|---|
| Smoking – 20 cigarettes a day | | 6 years |
| Overweight (by 15%) | | 2 years |
| Alcohol consumption (U.S. average) | | 1 year |
| All accidents combined | | 1 year |
| Motor vehicle accidents | 207 days | |
| Home accidents | 74 days | |
| Drowning | 24 days | |
| All natural hazards (earthquake, lightning, flood, etc.) | | 7 days |
| Medical radiation | | 6 days |
| Occupational Radiation Exposure | | |
| 0.3 rem/y from age 18 to 65 | 15 days | |
| 1 rem/y from age 18 to 65 | 51 days | |

[a] *Adapted from B L Cohen and L.S Lee, "Catalog of Risks Extended and Updated", Health Physics, Vol. 61, September 1991.*

**Table 2**
**Estimated Loss of Life Expectancy from Industrial Accidents [a]**

| Industry Type | Estimated Days of Life Expectancy Lost (Average) |
|---|---|
| All Industries | 60 |
| Agriculture | 320 |
| Construction | 227 |
| Mining and Quarrying | 167 |
| Transportation and Public Utilities | 160 |
| Government | 60 |
| Manufacturing | 40 |
| Trade | 27 |
| Services | 27 |

[a] Adapted from *B L. Cohen and L.S. Lee, "Catalog of Risks Extended and Updated", Health Physics, Vol 61, September 1991.*

### 11. What are the health risks from radiation exposure to the embryo/fetus?

During certain stages of development, the embryo/fetus is believed to be more sensitive to radiation damage than adults. Studies of atomic bomb survivors exposed to acute radiation doses exceeding 0.2 Gy (20 rads) during pregnancy show that children born after receiving these doses have a higher risk of mental retardation. Other studies suggest that an association exists between exposure to diagnostic x-rays before birth and carcinogenic effects in childhood and in adult life. Scientists are uncertain about the magnitude of the risk, Some studies show the embryo/fetus to be more sensitive to radiation-induced cancer than adults, but other studies do not. In recognition of the possibility of increased radiation sensitivity, and because dose to the embryo/fetus is involuntary on the part of the embryo/fetus, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker, see WISREG *"Instruction Concerning Prenatal Radiation Exposure."*

If an occupationally exposed woman declares her pregnancy in writing, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 5 mSv (500 mrem) for the total gestation period applies to the embryo/ fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and the possible loss of income. Because of these concerns, the declaration of pregnancy by a female radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn for any reason, for example, if the woman believes that her benefits from receiving the occupational exposure would outweigh the risk to her embryo/fetus from the radiation exposure.

### 12. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility cannot be caused by radiation at the levels allowed under HFS 157 occupational limits. There is a threshold below which these effects do not occur. Acute doses on the order of 0.1 Sv (10 rem) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 1.5 Gy (150 rads). The estimated threshold (acute) radiation dose for induction of permanent sterility is about 2 Gy (200 rads) for men and about 3.5 Gy (350 rads) for women (Refs. 1 and 4). These doses are far greater than the HFS 157 occupational dose limits for workers.

Although acute doses can affect fertility by reducing sperm count or suppressing ovulation, they do not have any direct effect on one's ability to function sexually. No evidence exists to suggest that exposures within the HFS 157 occupational limits have any effect on the ability to function sexually.

### 13. What are the HFS 157 occupational dose limits?

*For adults,* an annual limit not to exceed:

- 0.05 Sv (5 rem)) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.

- 0.5 Sv (50 rem) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.

- 0.15 Sv (15 rem) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.

0.5 Sv (50 rem) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

*For minor workers, the* annual occupational dose limits are 10 percent of the dose limits for adult workers.

*For protection of the embryo/fetus* of a declared pregnant woman, the dose limit is 5 mSv (0.5 rem) during the entire pregnancy.

The occupational dose limit for adult workers of 0.05 Sv (5 rem) TEDE is based on consideration of the potential for delayed biological effects. The 0.05 Sv (5-rem) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by DHFS. The limits for individual organs are below the dose levels at which early biological effects are observed in the individual organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of the possibility of greater sensitivity to radiation of the embryo/ fetus and the involuntary nature of the exposure.

## 14. What is meant by ALARA?

ALARA means "as low as is reasonably achievable." In addition to providing an upper limit on an individual's permissible radiation dose, HFS 157 requires that licensees and registrants establish radiation protection programs and use procedures and engineering controls to achieve occupational doses, and doses to the public, as far below the limits as is reasonably achievable. "Reasonably achievable" also means "to the extent practicable". What is practicable depends on the purpose of the job, the state of technology, the costs for averting doses, and the benefits. Although implementation of the ALARA principle is a required integral part of each licensee's or registrant's radiation protection program, it does not mean that each radiation exposure must be kept to an absolute minimum, but rather that "reasonable" efforts must be made to avert dose; In practice, ALARA includes planning tasks involving radiation exposure so as to reduce dose to individual workers and the work group.

There are several ways to control radiation doses, e.g., limiting the time spent in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose. The use of engineering controls, from the design of facilities and equipment to the actual set-up and conduct of work activities is also an important element of the ALARA concept.

An ALARA analysis should be used in determining whether the use of respiratory protection is advisable. In evaluating whether or not to use respirators, the goal should be to achieve the optimal sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure and related stresses caused by the use of respirators. Heat stress, reduced visibility, and reduced communication associated with the use of respirators could expose a worker to far greater risks than are associated with the internal dose avoided by use of the respirator. To the extent practical, engineering controls, such as containment and ventilation systems, should be used to reduce workplace airborne radioactive materials.

## 15. What are background radiation exposures?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., potassium-40) that contribute to

the radiation dose that we receive. The largest source of natural background radiation exposure is terrestrial radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, non-occupational exposure. Cosmic radiation originating in space contributes additional exposure. The use of x-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 3.6 mSv (0.36 rem). By age 20, the average person will have accumulated over 70 mSv (7 rem) of dose. By age 50, the total dose is up to 180 mSv (18 rem). After 70 years of exposure this dose is up to 250 mSv (25 rem).

**Table 3**
**Average Annual Effective Dose Equivalent to Individuals in the U.S.[A]**

| Source | Effective Dose Equivalent (mrems) | |
|---|---|---|
| Natural | | |
| Radon | 200 | |
| Other than Radon | 100 | |
| **Total** | | **300** |
| Nuclear Fuel Cycle | 0.05 | |
| Consumer Products [B] | 9 | |
| Medical | | |
| Diagnostic X-rays | 39 | |
| Nuclear Medicine | 14 | |
| **Total** | | **53** |
| **Total** | | **About 360 mrems / year** |

[A] Adapted from Table 8.1, National Council on Radiation Protection and Measurements, Ionizing Radiation Exposure of the Population of the United States, *NCRP Report No. 93,* September 1987.

[B] Includes building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, National Council on Radiation Protection and Measurements, Ionizing Radiation Exposure of the Population of the United States, *NCRP Report No. 93,* September 1987.

### 16. What are the typical radiation doses received by workers?

In 1993 the Nuclear Regulatory Commission (NRC) received reports on about a quarter of a million people who were monitored for occupational exposure to radiation. Almost half of those monitored had no measurable doses. The other half had an average dose of about 3.1 mSv (310 mrem) for the year. Of these, 93 percent received an annual dose of less than 10 mSv (1 rem) 98.7 percent received less than 20 mSv (2 rem); and the highest reported dose was for two individuals who each received between 50 and 60 mSv (5 and 6 rem).

Table 4 (page 17) lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1993 data. It is important to note licensees and registrants are required to sum external and internal doses and certain licensees are required to submit annual reports.

**Table 4**
**NRC's Licensees Reported Occupational Doses for 1994 [a]**

| Occupational Subgroup | Average Measurable Dose per Worker (millirems) |
|---|---|
| Industrial Radiography | 540 |
| Commercial Nuclear Power Reactors | 310 |
| Manufacturing and Distribution of Radioactive Materials | 300 |
| Low-Level Radioactive Waste Disposal | 270 |
| Independent Spent Nuclear Fuel Storage | 260 |
| Nuclear Fuel Fabrication | 130 |

[a] From Table 3.1 in C.T. Raddatz and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1993, "U.S. Nuclear Regulatory Commission, NUREG-0713, Volume 15, January 1995.

### 17. How do I know how much my occupational dose (exposure) is?

If you are likely to receive more than 10 percent of the annual dose limits, HFS 157 requires your employer, the licensee or registrant, to monitor your dose, to maintain records of your dose, and, to notify you in writing of your annual occupational dose. The purpose of this monitoring and reporting is so that DHFS can be sure that licensees and registrants are complying with the occupational dose limits and the ALARA principle.

Using individual monitoring devices monitors external exposures. These devices are required to be used if it appears likely that external exposure will exceed 10 percent of the allowed annual dose, i.e., 5 mSv (0.5 rem). The most commonly used monitoring devices are film badges, thermoluminescence dosimeters (TLDs), and optically stimulated luminescent dosimeter (OSL).

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in 1 year. Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material was in the air and the length of time during which the air was breathed.

### 18. What happens if a worker exceeds the annual dose limit?

If a worker receives a dose in excess of any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee or registrant is also required to file an overexposure report with DHFS and provide a copy to the individual who received the dose. The licensee or registrant may be subject to enforcement action as outlined in HFS 157, Subchapter XII - Enforcement, such as a fine (civil penalty), just as individuals are subject to traffic fines for exceeding a speed limit. Fines and, in instances of serious or repetitive exposures, suspension of a license or registration is possible.

Radiation protection limits do not define safe or unsafe levels of radiation exposure. Exceeding a limit does not mean that you will get cancer. For radiation protection purposes, it is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also considered to be higher. These

limits are similar to highway speed limits, If you drive at 70 mph, your risk is higher than at 55 mph, even though you may not actually have an accident. Those who set speed limits have determined that the risks of driving in excess of the speed limit are not acceptable. In the same way, HFS 157 establishes a limit for normal occupational exposure of 0.05 Sv (5 rem) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's or registrant's safety program has failed in some way. An Investigation is warranted to determine the cause and correct the conditions leading to the dose in excess of the limit.

**19. What is meant by a "planned special exposure"?**

A "planned special exposure" (PSE) is an infrequent exposure to radiation, separate from and in addition to the radiation received under the annual occupational limits. The licensee or registrant can authorize additional dose in any one year that is equal to the annual occupational dose limit as long as the individual's total dose from PSES does not exceed five times the annual dose limit during the individual's lifetime. For example, licensees or registrants may authorize PSEs for an adult radiation worker to receive doses up to an additional 0.05 Sv (5 rem) in a year above the 0.05 Sv (5 rem) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rem (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical.

Before the licensee or registrant authorizes a PSE, the licensee or registrant must ensure that the worker is informed of the purpose and circumstances of the planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may be present.

The licensee or registrant must also inform the department of the "planned special exposure"(including the date the planned special exposure occurred and the information required by HFS 157.31(6)) within 30 days following any "planned special exposure." (See the Nuclear Regulatory Commission's Regulatory Guide 8.35, "Planned Special Exposure, which is available from DHFS.)

**20. Why do some facilities establish administrative control levels that are below DHFS limits?**

There are two reasons. First, HFS 157 states that licensees and registrants must take steps to keep exposures to radiation ALARA. Specific approval from the licensee or registrant for workers to receive doses in excess of administrative limits usually results in more critical risk-benefit analyses as each additional increment of dose is approved for a worker. Secondly, an administrative control level that is set lower than HFS 157 limit provides a safety margin designed to help the licensee or registrant avoid doses to workers in excess of the limit.

**21. Why aren't medical exposures considered as part of a worker's allowed dose?**

HFS 157 exempts medical exposure, but equal doses of medical and occupational radiation have equal risks. Medical exposure to radiation is justified for reasons that are quite different from the reasons for occupational exposure, A physician prescribing an x-ray, for example, makes a medical judgment that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. This judgment may or may not be accepted by the patient. Similarly, each worker must decide on the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

Consider a worker who receives a dose of 0.03 Sv (3 rem) from a series of x-rays in connection with an injury or illness. This dose and any associated risk must be justified on medical grounds. If the worker had also received 0.02 Sv (2 rem) on the job, the combined dose of 0.05 Sv (5 rem) would in no way incapacitate the worker. Restricting the worker from additional job exposure during the remainder of the year would not have

any effect on the risk from the0.03 Sv (3 rem) already received from the medical exposure. If the individual worker accepts the risks associated with the x-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unreasonable to restrict the worker from employment involving exposure to radiation for the remainder of the year.

### 22. How should radiation risks be considered in an emergency?

Emergencies are "unplanned" events in which actions to save lives or property may warrant additional doses for which no particular limit applies. HFS 157 does not set any dose limits for emergency or lifesaving activities and states that nothing in HFS 157 "*shall be construed as limiting actions that may be necessary to protect health and safety.*"

Rare situations may occur in which a dose in excess of occupational limits would be unavoidable in order to carry out a lifesaving operation or to avoid a large dose to large populations. However, persons called upon to undertake any emergency operation should do so only on a voluntary basis and with full awareness of the risks involved.

For perspective, the U.S. Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practicable, be limited to 0.05 Sv (5 rem). The EPA further states that there are some emergency situations for which higher limits may be justified. The dose resulting from such emergency exposures should be limited to 0.1 Sv (10 rem) for protecting valuable property, and to 0.25 Sv (25 rem) for lifesaving activities and the protection of large populations. In the context of this guidance, the dose to workers that is incurred for the protection of large populations might be considered justified for situations in which the collective dose to others that is avoided as a result of the emergency operation is significantly larger than that incurred by the workers involved, Table 5 presents the estimates of the fatal cancer risk for a group of 1,000 workers of various ages, assuming that each worker received an acute dose of 0.25 Sv (25 rem)) in the course of assisting in an emergency. The estimates show that a .25 Sv (25 –rem) emergency dose might increase an individual's chances of developing fatal cancer from about 20% to about 21%.

**Table 5**
**Risk of Premature Death from Exposure to 25 Rem (0.25 Sv) Acute Dose**

| Age of Exposure (years) | Estimated Risk of Premature Death (Deaths per 1,000 Persons Exposed) |
|---|---|
| 20-30 | 9.1 |
| 30-40 | 7.2 |
| 40-50 | 5.3 |
| 50-60 | 3.5 |

From U.S Environmental Protection Agency, *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents*, EPA-400-R-92-001, May 1992.

### 23. How were radiation dose limits established?

The radiation dose limits established in HFS 157 are compatible with the Nuclear Regulatory Commission regulations, which are based on the recommendations of the ICRP and NCRP as endorsed in federal radiation protection guidance developed by the U.S. Environmental Protection Agency, "Radiation Protection Guidance for Federal Agencies for Occupational Exposure", *Federal Register,* Vol. 52, No. 17, January 27, 1987 (Ref.

12). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of ALARA should ensure that risks to workers are maintained indistinguishable from risks from background radiation.

**24. Several scientific reports have recommended that lower dose limits be established.**

Since the State of Wisconsin is an Agreement State, all dose limits are compatible with the Nuclear Regulatory Commission dose limits. Any recommendation to establish lower dose limits would be recommended by the Nuclear Regulatory Commission to all Agreement States including the State of Wisconsin.

Since publication of the Nuclear Regulatory Commission's proposed rule in 1986, the ICRP in 1990 revised its recommendations for radiation protection based on newer studies of radiation risks (Ref. 13), and the NCRP followed with a revision to its recommendations in 1993. The ICRP recommended a limit of 0.1 Sv (10 rem) effective dose equivalent (from internal and external sources), over a 5-year period with no more than 0.05 Sv (5 rem) in 1 year (Ref. 13). The NCRP recommended a cumulative limit in rem, not to exceed the individual's age in years, with no more than 0.05 Sv (5 rem) in any year (Ref. 14).

The Nuclear Regulatory Commission does not believe that additional reductions in the dose limits are required at this time. Because of the practice of maintaining radiation exposures ALARA (as low as is reasonably achievable), the average radiation dose to occupationally exposed persons is well below the limits in the current Title 10 Code of Federal Regulation Part 20 and the average doses to radiation workers are below the new limits recommended by the ICRP and the NCRP.

**25. What are the options if a worker decides that the risks associated with occupational radiation exposure are too high?**

If the risks from exposure to occupational radiation are unacceptable to a worker, he or she can request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are comparable to risks in other industries and are considered acceptable by the scientific groups that have studied them. An employer is not obligated to guarantee a transfer if a worker decides not to accept an assignment that requires exposure to radiation.

Any worker has the option of seeking other employment in a non-radiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, a worker may find different kinds of risk but will not necessarily find significantly lower risks in another job.

**26. Where can one get additional information on radiation risk?**

The following list suggests sources of useful information on radiation risk:

- The employer–the radiation protection or health physics office where a worker is employed.

- Wisconsin Department of Health and Family Services
  Radiation Protection Section
  1 West Wilson Street
  P.O. Box 2659
  Madison, WI 53701-2659
  Telephone: (608) 267-47-97

- U.S. Nuclear Regulatory Commission Headquarters
  Radiation Protection & Health Effects Branch
  Office of Nuclear Regulatory Research
  Washington, DC 20555
  Telephone: (301) 415-6187

- U.S. Department of Health and Human Services
  Center for Devices and Radiological Health
  1390 Piccard Drive, MS HFZ-1
  Rockville, MD 20850
  Telephone: (30 1) 443-4690

- U. S. Environmental Protection Agency
  Office of Radiation and Indoor Air
  Criteria and Standards Division
  401 M Street NW.
  Washington, DC 20460
  Telephone: (202) 233-9290

## APPENDIX REFERENCES


1. B.R. Scott et al., "Health Effects Model for Nuclear Power Plant Accident Consequence Analysis," Part I: Introduction, *Integration, and Summary,* U.S. Nuclear Regulatory Commission, NUREG/CR-42 14, Revision 2, Part I, October 1993. "

2. U.S. Environmental Protection Agency, *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-*001, May 1992.

3. International Commission on Radiological Protection, *Annals of the ICRP, Risks Associated with Ionising Radiation,* Volume 22, No. 1, Pergamon Press, Oxford, UK, 1991.

4. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation,* Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.

5. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR); *Sources, Effects and Risks of Ionizing Radiation,* Report E.88.IX.7, United Nations, New York, 1988.

6. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation,* United Nations, New York, 1993.

7. National Council on Radiation Protection and Measurements, New *Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates,* Proceedings of the Twenty-third Annual Meeting of the National Council on Radiation, Protection and Measurements Held on April 8-9, 1987 (1988).

8. National Council on Radiation Protection and Measurements, *Comparative Carcinogenicity of Ionizing Radiation and Chemicals,* NCRP Report No. 96, March 1989.

9. C.T. Raddatz and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1993, " U.S. Nuclear Regulatory Commission, NUREG-0713, Volume 15, January 1995.

10. B.L. Cohen and L.S. Lee, "Catalog of Risks Extended and Updated, " *Health Physics,* Vol. 61, September 1991.

11. National Council on Radiation Protection and Measurements, *Ionizing Radiation Exposure of the Population of the United States, NCRP Report* No. 93, September 1987.

12. U.S. Environmental Protection Agency, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," *Federal Register,* Vol. 52, No. 17, January 27, 1987.

13. International Commission on Radiological Protection, 1990 *Recommendations of the International Commission on Radiological Protection,* ICRP Publication 60, Pergamon Press, Oxford, UK, 1991.

14. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation, NCRP* Report No. 116, March 1993.

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Abrahamson, S,, *et al.,* "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, " Part II: *Scientific Bases for Health Effects Models,* U.S. Nuclear Regulatory Commission, NUREG/CR-4214, Rev. 1, Part II, May 1989

Abrahamson, S., *et al.,* "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Modifications of Models Resulting From Recent Reports on Health Effects of Ionizing Radiation, Low LET Radiation, " Part II: *Scientific Basis for Health Effects Models,* U.S, Nuclear Regulatory Commission, NUREG/CR-42 14, Rev. 1, Part II, Addendum 1, August 1991.

Abrahamson, S., *et al.,* "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Modifications of Models Resulting From Addition of Effects of Exposure to Alpha-Emitting Radionuclides, " Part II: *Scientific Bases for Health Effects Models,* U. S, Nuclear Regulatory Commission, NUREG/CR-4214, Rev. 1, Part II, Addendum 2, May 1993.

International Commission on Radiological Protection, *Radiation Protection,* Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, Pergamon Press, Oxford, UK, January 1977.

National Council on Radiation Protection and Measurements, *Public Radiation Exposure From Nuclear Power Generation in the United States,* NCRP Report No. 92, December 1987.

National Council on Radiation Protection and Measurements, *Exposure of the Population in the United States and Canada from Natural Background Radiation,* NCRP Report No. 94, December 1987. .

National Council on Radiation Protection and Measurements, *Exposure of the U.S. Population From Occupational Radiation,* NCRP Report No. 101, June 1989.

National Council on Radiation Protection and Measurements, *Risk Estimates for Radiation Protection,* NCRP Report No. 115, December 1993.

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National Safety Council, *Accident Facts, 1993 Edition,* Itasca, Illinois, 1993.

U.S. Environmental Protection Agency, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure, " *Federal Register,* Vol. 52, No. 17, January 27, 1987.

U.S. Nuclear Regulatory Commission, "Instruction Concerning Prenatal Radiation Exposure, " Regulatory Guide 8.13, Revision 2, December 1987.

U.S. Nuclear Regulatory Commission, "Monitoring Criteria and Methods To Calculate Occupational Radiation Doses, " Regulatory Guide 8.34, July 1992.

U.S. Nuclear Regulatory Commission, "Planned Special Exposures, " Regulatory Guide 8.35, June 1992.

U.S. Nuclear Regulatory Commission, "Radiation Dose to the Embryo/Fetus, " Regulatory Guide 8.36, July 1992.

# *Wisconsin Administrative Code Chapter HFS 157 - Radiation Protection Regulatory Guide 8.13*

*(WISREG 8.13)*

# Revision 1 – January 2002

# Instruction Concerning Prenatal Radiation Exposure

**Department of Health and Family Services**
**Division of Public Health**
**Radiation Protection Section**
**P.O Box 2659**
**Madison, WI 53701-2659**
**Phone: (608) 267-4797**
**Fax: (608) 267-3695**

**PPH 45024 (08/02)**

## INTRODUCTION

Wisconsin Administrative Code HFS 157.88(2)(b), requires that instruction given to workers "*be commensurate with potential radiological health protection problems present in the workplace and shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material that can be reasonably be expected to occur during the life of licensee's or registrant's activities*".

The Department of Health and Family Services regulations specified in HFS 157.22(8) "Dose Equivalent to an Embryo or Fetus" requires licensees or registrants to "*ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (500 mrem).*" HFS 157.22(8) also requires that "*a licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman.*" A declared pregnant woman is defined in HFS 157.03(90), *as a women who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception.*

This Wisconsin Regulatory Guide (WISREG) is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy.

Other sections of the Department of Health and Family Services' (DHFS) regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In HFS 157.25(2), "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," a licensee or registrant is required to monitor the occupational exposure to radiation sources under their control and supply and require the use of individual monitoring devices by *a declared pregnant woman likely to receive, in one year from sources of external to the body, a dose in excess of one mSv (0.1 rem).* According to HFS 157.31(7), "Records of Individual Monitoring Results," "*the licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.*"

## DISCUSSION

Exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increases as the dose increases. At the occupational dose limit for the whole body of 50 mSv (5 rem) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following *in utero* exposure is uncertain in that both negative and positive studies have been reported. The data from these studies *"are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult"* (The National Council on Radiation Protection and Measurements [NCRP] Report No. 116, (Ref. 2). DHFS has reviewed the available scientific literature and has concluded that the 5 mSv (500 mrem) limit specified in HFS 157.22(8) provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in Chapter HFS 157 "Radiation Protection", the woman must declare her pregnancy in writing to the licensee or registrant. A form letter for declaring pregnancy is provided in this guide, or the licensee or registrant may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

## REGULATORY POSITION

### 1. Who Should Receive Instruction.

Female workers who require training under HFS 157.88(2) should be provided with the information contained in this WISREG.

### 2. Providing Instruction

The occupational worker may be given a copy of this WISREG with its Appendix, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this WISREG and Appendix should also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to take some action in response to such a declaration.

Classroom instruction may supplement the written information. If the licensee or registrant provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this WISREG. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee or registrant (of radioactive materials or radiation producing machines) provides classroom training, the licensee or registrant should give workers the opportunity to ask questions about information contained in this WISREG. The licensee or registrant may take credit for instruction that the worker has received within the past year at other licensed or registered facilities or in other courses or training.

### 3. Licensee's or Registrant's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's or registrant's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's or registrant's policies, which may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy consistent with HFS 157.22(8).

The instruction should also identify whom to contact for additional information, as well as identify who should receive the written declaration of pregnancy. The recipient of the woman's declaration may be identified by name, position, or department.

### 4. Duration of Lower Dose Limits for the Embryo/Fetus

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing. If a declaration of pregnancy is withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. (If the declaration is not withdrawn, the written declaration shall be considered expired one year after submission.)

### 5. Substantial Variations Above a Uniform Monthly Dose Rate

According to HFS 157.22(8), "*A licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman.*" The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.5 mSv (50 mrem) to the embryo/fetus once the pregnancy is known (Ref. 2). In view of the NCRP recommendation, any monthly dose of less than 1 mSv (100 mrem) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee or registrants justification. However, the licensee or registrant should justify a monthly dose greater than 0.1 rem (1 mSv).

## IMPLEMENTATION

The purpose of this section is to provide information to licensees, registrants and applicants regarding DHFS's plans for using this WISREG. Unless a licensee, registrant or an applicant proposes an acceptable alternative method for complying with the specified portions of Chapter HFS 157 "Radiation Protection", the methods described in this WISREG will be used by DHFS in the evaluation of instructions to workers on the radiation exposure of pregnant women.

## REFERENCES

1. *WISREG* "Instructions Concerning Occupational Risk from Radiation Exposure", Rev. 0 June 2002

2. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

## APPENDIX

## QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE

### 1. Why am I receiving this information?

**Wisconsin Administrative Code Chapter HFS 157 'Radiation Protection'** [in HFS 157.88 (2), "Instructions to Workers"] requires that licensees or registrants instruct individuals working with licensed or registered radioactive materials in radiation protection, as appropriate for the situation. The instruction below describes information that occupational workers and their supervisors should know about the radiation exposure of the embryo/fetus of pregnant women.

**Chapter HFS 157 "Radiation Protection"** allows a pregnant woman to decide whether she wants to formally declare her pregnancy. This instruction provides information to help women make an informed decision whether to declare a pregnancy.

### 2. If I become pregnant, am I required to declare my pregnancy?

No. The choice whether to declare your pregnancy is completely voluntary. If you choose to declare your pregnancy, you must do so in writing and a lower radiation dose limit will apply to your embryo/fetus. If you choose not to declare your pregnancy, you and your embryo/fetus will continue to be subject to the same radiation dose limits that apply to other occupational workers.

### 3. If I declare my pregnancy in writing, what happens?

If you choose to declare your pregnancy in writing, the licensee or registrant must take measures to limit the dose to your embryo/fetus to 5 millisievert (500 mrem) during the entire pregnancy. This is one-tenth of the dose that an occupational worker may receive in a year. If you have already received a dose exceeding 5 mSv (500 mrem) in the period between conception and the declaration of your pregnancy, an additional dose of 0.5 mSv (50 mrem) is allowed during the remainder of the pregnancy. In addition, HFS 157.22(8), "Dose to an Embryo/Fetus," requires licensees or registrants to make efforts to avoid substantial variation above a uniform monthly dose rate so that all the 5 mSv (500 mrem) allowed dose does not occur in a short period during the pregnancy.

This may mean that, if you declare your pregnancy, the licensee or registrant may not permit you to do some of your normal job functions if those functions would have allowed you to receive more than 5 mSv (500 mrem) and you may not be able to have some emergency response responsibilities.

### 4. Why do the regulations have a lower dose limit for the embryo/fetus of a declared pregnant woman than for a pregnant worker who has not declared?

A lower dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure. Several scientific advisory groups have recommended (References 1 and 2) that the dose to the embryo/fetus be limited to a fraction of the occupational dose limit.

### 5. What are the potentially harmful effects of radiation exposure to my embryo/fetus?

The occurrence and severity of health effects caused by ionizing radiation are dependent upon the type and total dose of radiation received, as well as the time period over which the exposure was received. The main concern is embryo/fetal susceptibility to the harmful effects of radiation such as cancer.

**6. Are there any risks of genetic defects?**

Although radiation injury has been induced experimentally in rodents and insects, and in the experiments was transmitted and became manifest as hereditary disorders in their offspring, radiation has not been identified as a cause of such effect in humans. Therefore, the risk of genetic effects attributable to radiation exposure is speculative. For example, no genetic effects have been documented in any of the Japanese atomic bomb survivors, their children, or their grandchildren.

**7. What if I decide that I do not want any radiation exposure at all during my pregnancy?**

You may ask your employer for a job that does not involve any exposure at all to occupational radiation dose, but your employer is not obligated to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, your embryo/fetus will receive some radiation dose [(on average (0.75 mSv (75 mrem))] during your pregnancy from natural background radiation.

DHFS has reviewed the available scientific literature and concluded that the 5 mSv (500 mrem) limit provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers. If this dose limit is exceeded, the total lifetime risk of cancer to the embryo/fetus may increase incrementally. However, the decision on what level of risk to accept is yours. More detailed information on potential risk to the embryo/fetus from radiation exposure can be found in References 2-10.

**8. What effect will formally declaring my pregnancy have on my job status?**

Only the licensee or registrant can tell you what effect a written declaration of pregnancy will have on your job status. As part of your radiation safety training, the licensee or registrant should tell you the company's policies with respect to the job status of declared pregnant women. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer and ask what a declaration of pregnancy would mean specifically for you and your job status.

In many cases you can continue in your present job with no change and still meet the dose limit for the embryo/fetus. For example, most commercial power reactor workers (approximately 93%) receive, in 12 months, occupational radiation doses that are less than 5 mSv (500 mrem) (Ref. 11). The licensee or registrant may also consider the likelihood of increased radiation exposures from accidents and abnormal events before making a decision to allow you to continue in your present job.

If your current work might cause the dose to your embryo/fetus to exceed 5 mSv (500 mrem), the licensee or registrant has various options. It is possible that the licensee or registrant can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee do a small part of the job that would otherwise account for some of your radiation exposure.

**9. What information must I provide in my written declaration of pregnancy?**

You should provide, in writing, your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to the licensee or registrant. A form letter that you can use is included at the end of these questions and answers. You may use that letter, a form letter the licensee or registrant has provided to you, or write your own letter.

**10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?**

DHFS's rule does not require that you provide medical proof of your pregnancy. However, DHFS does not preclude the licensee or registrant from requesting medical documentation of your pregnancy, especially if a change in your duties is necessary in order to comply with the 5 mSv (500 mrem) dose limit.

**11. Can I tell the licensee or registrant orally rather than in writing that I am pregnant?**

No. The regulations require that the declaration must be in writing.

**12. If I have not declared my pregnancy in writing, but the licensee or registrant suspects that I am pregnant, do the lower dose limits apply?**

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The United States Supreme Court has ruled (in *United Automobile Workers International Union v. Johnson Controls, Inc.*, 1991) that "Decisions about the welfare of future children must be left to the parents who conceive, bear, support, and raise them rather than to the employers who hire those parents" (Reference 7). The Supreme Court also ruled that your employer may not restrict you from a specific job "because of concerns about the next generation." Thus, the lower limits apply only if you choose to declare your pregnancy in writing.

**13. If I am planning to become pregnant but am not yet pregnant and I inform the licensee or registrant of that in writing, do the lower dose limits apply?**

No. The requirement for lower limits applies only if you declare in writing that you are already pregnant.

**14. What if I have a miscarriage or find out that I am not pregnant?**

If you have declared your pregnancy in writing, you should promptly inform the licensee or registrant in writing that you are no longer pregnant. However, if you have not formally declared your pregnancy in writing, you need not inform the licensee or registrant of your non-pregnant status.

**15. How long is the lower dose limit in effect?**

The dose to the embryo/fetus must be limited until you withdraw your declaration in writing or you inform the licensee or registrant in writing that you are no longer pregnant. If the declaration is not withdrawn, the written declaration will be considered expired one year after submission.

**16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?**

Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limit for the embryo/fetus no longer applies.

**17. What if I work under contract at a registered or licensed facility?**

The regulations state that you should formally declare your pregnancy to the licensee or registrant in writing. Once declared the licensee or registrant has the responsibility to limit the dose to the embryo/fetus.

## 8. Where can I get additional information?

The references in this Appendix contain helpful information, especially Reference 3, *WISREG* "Instructions Concerning Occupational Risk from Radiation Exposure" for general information on radiation risks. The licensee or registrant should be able to give this document to you or you may contact the Department of Health and Family Services at (608) 267-4797.

For information on legal aspects, see Reference 7, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children—What Can the Employer Do?" which is an article in the journal *Radiation Protection Management*.

You may also telephone the State of Wisconsin, Department of Health and Family Services, Radiation Protection Section at (608) 267-4797 for further information.

**Note:** Single copies of regulatory guides may be attained by contacting the State of Wisconsin, Department of Health and Family Services, Radiation Protection Section at (608) 267-4797 or by mail at P.O. Box 2659, Madison, WI 53701-2659.

## REFERENCES FOR APPENDIX


1. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

2. International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Ann. ICRP 21: No. 1-3, Pergamon Press, Oxford, UK, 1991.

3. *WISREG* "Instructions Concerning Occupational Risk from Radiation Exposure", Rev. 0 June 2002.

4. Committee on the Biological Effects of Ionizing Radiations, National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation* (BEIR V), National Academy Press, Washington, DC, 1990.

5. United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

6. R. Doll and R. Wakeford, "Risk of Childhood Cancer from Fetal Irradiation," *The British Journal of Radiology*, 70, 130-139, 1997.

7. David Wiedis, Donald E. Jose, and Timm O. Phoebe, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children—What Can the Employer Do?" *Radiation Protection Management*, *11,* 41-49, January/February 1994.

8. National Council on Radiation Protection and Measurements, *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child*, NCRP Commentary No. 9, Bethesda, MD, 1994.

9. National Council on Radiation Protection and Measurements, *Risk Estimates for Radiation Protection*, NCRP Report No. 115, Bethesda, MD, 1993.

10. National Radiological Protection Board, *Advice on Exposure to Ionising Radiation During Pregnancy*, National Radiological Protection Board, Chilton, Didcot, UK, 1998.

11. M.L. Thomas and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996," Twenty-Ninth Annual Report, NUREG-0713, Vol. 18, USNRC, 1998.

## EXAMPLE OF FORM LETTER FOR DECLARING PREGNANCY

The following form letter is provided as an example of a written declaration of pregnancy. This form letter may be used, or one the licensee or registrant has provided, or you may write your own letter.

---

## DECLARATION OF PREGNANCY

To:_____

In accordance with the State of Wisconsin, Department of Health and Family Services Administrative Code at HFS 157.22(8) "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in *(only the month and year need be provided)*.

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 5 mSv (500 mrem) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____
*(Your signature)*

_____
*(Your name printed)*

_____
*(Date)*

# 6

# STATE OF WISCONSIN
# HEALTH AND FAMILY SERVICES

## Radiation Protection Section

**Radioactive Materials Program Procedure No. 3.01**

**Scheduling of Inspections**

**Prepared By:**_____**Date**_____
**Paul J. Caleb, Nuclear Engineer**

**Reviewed By:**_____**Date**_____
**Cheryl K. Rogers, Materials Program Supervisor**

**Approved By:**_____**Date**_____
**Paul S. Schmidt, Chief**

**Effective Date**_____

## Table of Contents

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure applies to the scheduling of inspections based on the priorities assigned to the various licensed activities.

1.1.2 This performance based inspection program gives licensees credit for good performance by extending the interval of the next inspection and requires poor performers to be inspected more frequently.

1.1.3 Core and non-core inspection priorities and a program of special inspection activities are established for all licensees.

### 1.2 References

1.2.1 NRC Inspection Manual, Chapter 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States,' and Inspection of Agreement State Licensees Operating Under 10 CFR Part 150.20"

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

1.2.3 Chapter HFS 157 'Radiation Protection'

1.2.4 WI Stats. 254.31-.45

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

### 1.4 Hardcopy Files

### 1.5 Definitions

1.5.1 Core Inspection means all initial inspections of priority 1, 2, 3, and 5 licensees and all routine inspections of priority 1, 2, or 3 licensees.

1.5.2 Initial Inspection means the first inspection after a license is issued.

1.5.3 Inspection means the act of assessing licensee performance to determine if radioactive materials are used safely; and, whether the licensee is in compliance with rules, regulations, statutes, license conditions, and the licensee commitments submitted in support of the application for license and incorporated in the license by "tie-down" conditions. Inspections include a visit to a licensee's facility and/or job site, observation of licensed activities, interaction with licensee personnel, and reporting of the inspection findings. Pre-licensing visits or telephone communications are not inspections.

1.5.4 Inspection Priorities means the inspection priority assigned to a license is the frequency of routine inspections expressed in years, i.e., a priority 1 license is inspected every year. The priority is based on the potential radiation hazard of the licensee's program. A priority 1 license represents the greatest risk to the health and safety of the public and the environment and therefore, requires the most frequent inspection.

1.5.5 Non-Core Inspections means routine inspections of priority 5 licensees, other than initial inspections.

1.5.6 Reactive Inspection means a special inspection in response to an incident, allegation, or special information obtained by the department, e.g., medical events. These inspections may focus on one or several issues and need not examine the rest of a licensee's program. A reactive inspection counts as a routine inspection only if the total licensed program is evaluated.

1.5.7 Routine Inspection means a periodic, comprehensive inspection performed at a specified frequency.

1.5.8 Special Inspection means those inspections where special guidance is needed. Those activities include: (1) inspections of expired licenses, terminated licenses, and licenses undergoing decommissioning (2) inspections of significantly expanded programs; (3) reciprocity inspections; (4) temporary job-site or field site inspections; (5) team inspections (6) inspections of abandoned licenses; and, (7) general licensee's program inspections.

1.5.9 Team Inspections means inspections conducted by three or more inspectors or any inspection that includes an inspector from outside of WI (other than NRC Agreement State Program representatives). A team inspection can be a routine inspection of a major licensee or a reactive inspection in response to a particular incident or event. Team inspections don't include those where a supervisor accompanies an inspector in order to evaluate the inspectors performance.

1.5.10 Telephone Contact means contacts by telephone and documented in the license file, to determine the status of a licensee's activities, to assess compliance or to exchange information with the licensee. Telephone contacts are not considered inspections.

1.5.11 Tie-down condition means a written commitment made by the applicant in an application for a license or amendment to a license that is made a condition of the license, i.e., the commitment is "tied-down" as a legal requirement. Signed letters or signed fax transmissions can be used.

## RESPONSIBILITIES

### 2.1 Program Assistant

Prior to the start of each calendar quarter, provide the Materials Program Supervisor (MPS) with a list of inspections due during the calendar quarter. The list should include all routine and initial inspections; the priority of each license; and the date of the last inspection or that this is an initial inspection.
Maintains the hardcopy files and the computer based letters, forms and reports files.

### 2.2 Nuclear Engineer

Conducts inspections, and recommends extension or reduction of inspection frequency.
Reviews applications for license and recommends license priorities.

### 2.3 Materials Program Supervisor (MPS)

Prepares inspection schedules and assigns inspectors on a quarterly basis; approves extensions or reduction of inspection frequency; and, approves the assignment of license priorities.
Determines if a reactive or special inspection is warranted; should be performed promptly or can be included in the next routine inspection; and, initiates an inspection, if appropriate.
Reports inspection and licensing statistics to the Radiation Protection Section Chief on a quarterly basis.

## 3.0 PROCEDURE

### 3.1 License Priorities

Each license is assigned a primary program code which sets the inspection priority and schedules the initial inspection. Attachment 3.01-1 "Inspection Priority By Program Codes" is a listing of materials programs and their associated inspection priorities.
If a license involves more than one type of use, the type associated with the highest priority (most frequent) inspection shall establish the inspection priority.
An initial inspection need not be performed for a new license that has been issued within 6 months of the expiration of a similar license.

### 3.2 Inspection Priorities

The performance of Reactive Inspections shall receive first priority in the inspection program followed by the performance of Core and Special Inspections. Non-Core inspections shall be performed as resources permit.

## 3.3 Routine Inspections

### 3.3.1 Core Inspections

All initial inspections, regardless of the license priority, are to be conducted within 6 months of the receipt of licensed material; within 6 months of beginning licensed activities; or within 1 year of license issuance, which ever comes first. Licensees are required by License Condition to inform the MPS of their first receipt of licensed material.

Initial inspections shall be announced.

Routine inspections of licenses in priorities 1, 2, and 3 shall be conducted at intervals in years corresponding to the inspection priority.

The inspection date may vary by +/- 25 % from the specified date; however, the last inspection date must be used when scheduling the next inspection.

Routine inspections shall be unannounced.

### 3.3.2 Non-Core Inspections

Priority 5 licenses shall be inspected at 5 year intervals.

The inspection date may vary by +/- 1 year from the specified date; however, the last inspection date must be used when scheduling the next inspection.

The inspections shall be unannounced.

## 3.4 Extension of Inspection Frequency

Based on good licensee performance, the interval between inspections may be extended beyond that specified by the priority system. Good licensee performance is evidenced by a well-managed and effective radiation safety program that has a history of compliance. The inspection frequency shall be extended, for licensees meeting the following conditions:

1. the violations identified during the current inspection and preceding inspection met the criteria for documentation on an WI Form 591 or WI Inspection Letter (RMPP No. 3.05) and there were no more than two severity Level IV violations per inspection, and

2. the licensee has not had a significant program change since the preceding inspection. Significant program changes include changes in the scope or type of operation; changes in the authorized materials or possession limits; changes in key personnel, or; changes in location of use.

Licensees that meet the above criteria shall have their inspection interval extended as follows:

| | |
|---|---|
| Priority 1 | increased up to 2 years |
| Priority 2 | increased up to 3 years |
| Priority 3 | Increased up to 5 years |
| Priority 5 | Increased up to 7 years |

This extension is only for the next inspection, the routine designated inspection priority does not change.

The decision to extend the inspection frequency shall be made immediately after the completion of the routine inspection report.

The decision to extend the inspection frequency should be documented on the inspection report by the inspector and approved and initialed by the Materials Program Supervisor.

### 3.5 Reduction of Inspection Frequency

Based on poor licensee performance the interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system. Poor performance is evidenced by moderate to severe problems in the radiation safety program; a poor compliance history, or; lack of management involvement or control over the radiation safety program. Reduction of inspection frequency shall be considered for licensees that meet one or more of the following conditions (this list is not all inclusive):

1. a Severity Level I, II, or III violation on the most recent inspection, or
2. issuance of an Order or escalated enforcement on the most recent inspection, or
3. a "management paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (management paragraph is a paragraph that requires the licensee to address adequate management

control over the licensed program), or

4. an event requiring a reactive inspection, or
5. repetitive violations.

Licensees that meet the above criteria may have their inspection interval reduced by any length. A follow-up inspection should be conducted within 6 months of receipt of licensee's corrective action(s) following an escalated enforcement action. (See RMPP 3.05.)

The reduction shall be valid only until the next inspection, but management shall consider the results of the next inspection and determine if the reduced frequency should be continued, changed or returned to normal.

The decision to reduce the inspection frequency should be documented on the inspection report by the inspector and approved and signed by the Materials Program Supervisor.

## 3.6 Reactive Inspections

Reactive inspections receive first priority in the inspection program.

Following the receipt of notification of an incident, allegation or special information such as a medical event, the Materials Program Supervisor, or designee, shall determine if an immediate inspection is warranted or if the issue is best covered during the next scheduled inspection.

A reactive inspection counts as a scheduled inspection only if the total licensed program is evaluated.

## 3.7 Special Inspections

The following activities require special inspections:

1. Expired and Terminated Licenses

   In accordance with the criteria outlined in RMPP No. 2.05 "License Termination" notification that a license has expired or is being terminated may require that an inspection be conducted within 30 days of the date of notification.

   This is an announced inspection.

2. Reciprocity Inspections

Receipt of a request for reciprocity requires that an inspection should be performed at a frequency based on priority for program codes as follows:

***100% of all service licensees who perform teletherapy and panoramic irradiator source installations, changes, and removals are to be inspected each year.***

| | |
|---|---|
| Priority 1 | 50% of licensees inspected each year |
| Priority 2 | 50% of licensees inspected each year |
| Priority 3 | 30% of licensees inspected each year |
| All others | 10% of licensees inspected each year |

The priority of the license, the location of the activity and the time to be spent in the state should be factors in any such determination.

In order to meet the inspection goals for inspection of reciprocity activities unannounced inspection of actual field work locations have preference over announced inspections of actual field work.

## 4.0 RECORDS

### 4.1 Hardcopy

### 4.2 Computer Based

The computer based letters, forms and reports used on the ACCESS data base are located in: L:\Agreement State

## 5.0 ATTACHMENTS

3.01-1 "Inspection Priority by Program Code"

# Enclosure 1: Inspection Priority by Program Codes

| Program | Category Title | Remarks | Priority |
|---|---|---|---|
| 01100 | Academic Type A Broad | Committee-approved users | 2 |
| 01110 | Academic Type B Broad | Radiation Safety Officer- (RSO-) approved users | 3 |
| 01120 | Academic Type C Broad | Named users | 5 |
| 02110 | Medical Institution Broad | Hospitals only | 1 |
| 02120 | Medical Institution - Quality Management Program (QMP) required | Hospitals, clinics | 3 |
| 02121 | Medical Institution - no QMP required | | 5 |
| 02200 | Medical Private Practice - QMP required | | 3 |
| 02201 | Medical Private Practice - no QMP required | | 5 |
| 02210 | Eye Applicators Strontium-90 (Sr-90) | Hospitals or physicians' offices | 3 |
| 02220 | Mobile Nuclear Medicine Service | (Primary code) | 2 |
| 02230 | High-, Medium-, and Pulsed- Dose Rate Remote Afterloaders | | 1 |
| 02231 | Mobile High-, Medium-, and Pulsed-Dose Rate Remote Afterloaders | | 1 |
| 02240 | Mobile Therapy | Hospital, Health Centers | 2 |
| 02300 | Teletherapy | Human use only | 3 |
| 02310 | Stereotactic Radiosurgery | Gamma Knife, Hospital, Health Centers | 1 |
| 02400 | Veterinary Nonhuman | | 5 |
| 02410 | In-Vitro Testing Laboratories | | 5 |
| 02500 | Nuclear Pharmacies | | 1 |
| 02511 | Medical Product Distribution - 32.72 | Prepared Radiopharmaceuticals | 3 |
| 02513 | Medical Product Distribution - 32.74 Sources and Devices | Therapy sources, calibration and reference sources | 3 |
| 03110 | Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources | | 3 |
| 03111 | Well Logging Byproduct and/or SNM Sealed Sources Only | | 3 |
| 03112 | Well Logging Byproduct Only - Tracers Only | | 3 |
| 03113 | Field Flooding Studies | | 3 |
| 03120 | Measuring Systems, Fixed Gauges | | 5 |
| 03121 | Measuring Systems, Portable Gauges (includes Industrial Lixiscope) | | 5 |
| 03122 | Measuring Systems Analytical Instruments | | 7 |
| 03123 | Measuring Systems Gas Chromatographs | | 7 |

| | | | |
|---|---|---|---|
| 03124 | Measuring Systems Other | | 7 |
| 03211 | Manufacturing and Distribution Type A Broad | | 1 |
| 03212 | Manufacturing and Distribution Type B Broad | | 3 |
| 03213 | Manufacturing and Distribution Type C Broad | | 5 |
| 03214 | Manufacturing and Distribution Other | | 3 |
| 03218 | Nuclear Laundry | | 2 |
| 03219 | Decontamination Services | | 2 |
| 03220 | Leak Test Services Only | | 7 |
| 03221 | Instrument Calibration Services Only - Self- Shielded | | 5 |
| 03222 | Instrument Calibration Services Only - Other | | 3 |
| 03225 | Other Services - includes teletherapy, irradiator, and gauge services | | 3 |
| 03231 | Waste Disposal - Burial | | 1 |
| 03232 | Waste Disposal Service Prepackaged Only | | 2 |
| 03233 | Waste Disposal Service Incineration | | 1 |
| 03234 | Waste Disposal Service Processing and/or Repackaging | | 1 |
| 03235 | Incineration-Noncommercial (Secondary Code) | | |
| 03240 | General License Distribution - 32.51 | Generally licensed gauges, other | 5 |
| 03241 | General License Distribution - 32.53 | Hydrogen-3(H-3), Promethium-147 (Pm-147) signs or markers | 5 |
| 03242 | General License Distribution - 32.57 | Americium-241 (Am-241) calibration sources | 5 |
| 03243 | General License Distribution - 32.61 | Sr-90 ice detection | 5 |
| 03244 | General License Distribution - 32.71 | In-vitro kits | 5 |
| 03250 | Exempt Distribution-32.11 | Exempt concentrations. Includes broad | 5 |
| 03251 | Exempt Distribution-32.14 | H-3, Pm-147, and other isotopes in 10 CFR 30.15 | 5 |
| 03252 | Exempt Distribution, Resins - 32.17 | Scandium-46(Sc-46) resins | 5 |
| 03253 | Exempt Distribution-32.18 Small Quantities | Byproduct material in processed chemicals, elements, compounds, mixtures, tissue samples, etc. | 5 |
| 03254 | Exempt Distribution-32.22 | Self-luminous products | 5 |

| | | | |
|---|---|---|---|
| 03255 | Exempt Distribution-32.26 | Smoke detectors | 5 |
| 03310 | Industrial Radiography, Fixed | | 1 |
| 03320 | Industrial Radiography, Temporary Jobsites | | 1 |
| 03510 | Irradiators Self-Shielded Less Than 370 TBq (10,000 curies) | Includes blood irradiators | 5 |
| 03511 | Irradiators - Other Less than 370 TBq (10,000 curies) | Panoramic; includes converted teletherapy units | 3 |
| 03520 | Irradiators Self-Shielded Greater than 370 TBq (10,000 curies) | | 3 |
| 03521 | Irradiators - Other Greater than 370 TBq (10,000 curies) | | 1 |
| 03610 | Research and Development, Type A Broad | Committee-approved users | 2 |
| 03611 | Research and Development, Type B Broad | RSO-approved users | 3 |
| 03612 | Research and Development, Type C Broad | Named users | 5 |
| 03613 | Research and Development, Broad - Multisite-Multiregional | | 1 |
| 03620 | Research and Development, Other | | 5 |
| 03710 | Civil Defense | | 5 |
| 03800 | Byproduct Material Possession-Only - Permanent Shutdown | | 2 |
| 03810 | Byproduct Material Standby - No Operations | | 2 |
| 03900 | Decommissioning of Byproduct Material Facilities | | 1 |
| 11200 | Source Material - Other Less than 150 Kilograms | | 5 |
| 11210 | Source Material- Shielding | | 7 |
| 11220 | Source Material- Military Munitions-Indoor Testing | | 5 |
| 11221 | Source Material- Military Munitions-Outdoor Testing | | 3 |
| 11230 | Source Material General License Distribution - 10 CFR 40.34 | | 5 |
| 11300 | Source Material - Other Greater than 150 Kilograms | Includes munition production, subcritical assembly, and other | 3 |
| 11700 | Rare-Earth Extraction and Processing | | 3 |
| 11800 | Source Material Possession-Only - Permanent Shutdown | | 2 |
| 11810 | Source Material Standby - No Operations | | 2 |
| 11900 | Decommissioning of Source Material Facilities | | 1 |
| 21310 | Critical Mass Material - University | | 5 |

| | | |
|---|---|---|
| 21320 | Critical Mass Material - Other Than Universities | 5 |
| 21325 | Decommissioning of Critical Mass - Other Than Fuel Fabrication | 1 |
| 22110 | SNM Plutonium - Unsealed Less than Critical Mass | 2 |
| 22111 | SNM U-235 and/or U-333 - Unsealed Less than Critical Mass | 2 |
| 22120 | SNM Plutonium - Sealed Neutron Source Less than 200 Grams | 5 |
| 22130 | Power Sources with Byproduct and/or SNM | 7 |
| 22140 | SNM Plutonium - Sealed Sources in Devices | 5 |
| 22150 | SNM Plutonium - Sealed Sources Less than Critical Mass | 5 |
| 22151 | SNM U-235 and/or U-233 Sealed Sources Less than Critical Mass | 5 |
| 22160 | Pacemaker Byproduct, and/or SNM - Medical Institution | 7 |
| 22161 | Pacemaker Byproduct, and/or SNM - Individual | 7 |
| 22162 | Pacemaker Byproduct and/or SNM - Manufacturing and Distribution | 1 |
| 22170 | SNM General License Distribution - 70.39 | 5 |
| 22200 | Decommissioning of Other SNM Facilities - Less than Critical Mass | 1 |
| 23300 | SNM Possession-Only (Non-Fuel)-Permanent Shutdown | 2 |
| 23310 | SNM Standby (Non-Fuel)-No Operations | 2 |

# STATE OF WISCONSIN
# HEALTH AND FAMILY SERVICES

## Radiation Protection Section

**Radioactive Materials Program Procedure No. 3.02**

**Inspection Preparation**

**Prepared By:**_____**Date:**_____
**Paul J. Caleb**

**Reviewed By:**_____**Date:**_____
**Cheryl K. Rogers, Materials Program Supervisor**

**Approved By:**_____**Date:**_____
**Paul Schmidt, Radiation Protection Section Chief**

**Effective Date**_____

## Table of Contents

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure applies to an inspector preparing for the performance of an inspection.

1.1.2 Preparation for conducting special, initial and routine core and non-core inspections are covered.

1.1.3 The types of radiation detection instruments available for use during an inspection are identified.

### 1.2 References

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

1.2.2 Chapter HFS 157 'Radiation Protection"

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

### 1.4 Hardcopy Files

### 1.5 Definitions

1.5.1 Core Inspection means all initial inspections of priority 1, 2, 3 and 5 licensees and all routine inspections of priority 1, 2, or 3 licensees.

1.5.2 Inspection Field Notes means a handwritten or computer generated inspection checklist/report used to document the inspection.

1.5.3 Initial Inspection means the first inspection after a license is issued.

1.5.4 Inspection means the act of assessing licensee performance to determine if radioactive materials are used safely, and, whether the licensee is in compliance with WI Rules, statutes, license conditions, and the license commitments submitted in support of the application for license and incorporated in the license by "tie-down" conditions. Inspections include a visit to a licensee's facility and/or job site, observation of licensed activities, interaction with licensee personnel, and reporting of the inspection findings. Pre-licensing visits or telephone communications are not inspections.

1.5.5 Non-Core Inspection means routine inspections of priority 5 licensees.

1.5.6 Routine Inspection means a periodic, comprehensive inspection performed at a specified frequency.

1.5.7 Reactive Inspection means a non-routine inspection (investigation) in response to an incident, allegation, or special information obtained by the Department, e.g., a report of a medical event. These inspections may focus on one or several issues and need not examine the rest of a licensee's program. If all of the activities normally reviewed during a routine inspection are not reviewed then the requirement to inspect the facility at an established frequency is not satisfied.

1.5.8 Special Inspection means those inspection activities where special guidance is needed.

These activities include:

- inspection of expired licenses, terminated licenses, and licenses undergoing decommissioning
- inspection of significantly expanded programs
- reciprocity inspections
- temporary job-site or field site inspections
- team inspections
- inspections of abandoned licenses
- general license's program inspection

## 2.0 RESPONSIBILITIES

### 2.1 Program Assistant

2.1.1 At least 15 working days prior to the start of each calendar quarter, provides the Materials Program Supervisor, with a list of inspections that are due during that calendar quarter.

2.1.2 Maintains and organizes the computer based inspection field notes.

2.1.3 Maintains and organizes the hardcopy inspection field notes.

### 2.2 Nuclear Engineers

2.2.1 Properly prepares for each assigned inspection.

2.2.2 Prepares an inspection plan for core, reactive and special inspections.

### 2.3 Materials Program Supervisor

2.3.1 Assigns inspections for the next calendar quarter to the qualified members of the inspection staff.

2.3.2 Reviews and approves or requires modification of an inspection plan(s).

## 3.0 PROCEDURE

### 3.1 General

This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection. For example, use of an appropriate NRC or WI Regulatory Guide (WISREG).

### 3.2 Initial Inspections

3.2.1 All initial inspections are to be announced. Initial inspections are conducted within six months following receipt of the notice from the licensee that licensed material has been received or one year following the issuance of the license whichever occurs first.

3.2.2 The following items shall be reviewed and noted on the inspector's inspection plan:

a) Application: location of facility and use; authorized isotopes, use, and quantities; authorized users, user training and/or experience; facilities for use and storage; commitments; disposal; and, instrumentation - fixed and portable.

b) License: Differences between the license and the application, if any; and, "tie-down" commitments and information submitted by the licensee that is not a "tie-down" condition in the license.

c) Rule: Applicable sections of Chapter HFS 157 'Radiation Protection.'

3.2.3 Use appropriate NRC or Wisconsin guidance to determine specific requirements that should be reviewed during the inspection and include them in the inspection plan.

3.2.4 Review Information Notices and Office of State and Tribal Program notices to determine if there have been any recent issues concerning this type of license, that should be reviewed during this inspection. Include any that are appropriate in the inspection plan.

3.2.5 Obtain the appropriate inspection field notes, calibrated instrumentation, inspection plan. Remember to wear your dosimetry.

### 3.3 Routine Inspections

All routine inspections are unannounced unless specific instructions are received from the Materials Program Supervisor that an inspection is to be announced.

### 3.3.1 Core Licensees

The following items shall be reviewed and noted on the inspection plan:

3.3.1.1 License File: Determine if the license has been amended since the last inspection. Note differences such as increased scope of operations, changes in principal staff, new/different facilities; new "tie-down" commitments.

3.3.1.2 Regulatory Requirements: Determine changes in regulatory requirements since the last inspection that affect the licensee's program.

3.3.1.3 Results of Last Inspection: Review the results of the last inspection. If any enforcement action was taken or if WI Form 591 with minor noncompliance items was issued, note the items that the licensee committed to correct.

3.3.1.4 Guidance: Use appropriate NRC or Wisconsin guidance to determine specific requirements that should be reviewed during the inspection and include them in the inspection plan.

3.3.1.5 Notices: Review the Information Notices files and OSTP notices to determine if there have been any recent issues concerning this type licensee that should be reviewed during this inspection.

3.3.1.6 Other: Obtain the appropriate inspection field notes, calibrated instrumentation, inspection plan. Remember your dosimetry.

### 3.3.2 Non-Core Licensees

Priority 5 Inspections: the same procedure as for core inspections should be used when preparing for the inspection. An inspection plan is not required.

## 3.4 Reactive & Special Inspections

Reactive and special inspections focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections shall be under the direct supervision of the Material Program Supervisor. Narrative reports shall be prepared for reactive and special inspections.

# 4.0 RECORDS

## 4.1 Hardcopy

4.1.1 Once the inspection field notes are completed and any necessary correspondence has been mailed to the licensee, the inspection plan may be discarded.

## 4.2 Computer Based

4.2.1 The Access database is located in: L:/EEP_Radiatio/

4.2.2 A template inspection plan is located in: L:/EEP_Radiatio/Agreement State Program

## 5.0 ATTACHMENTS TO RMPP No. 3.02

3.02-1 Inspection Guidance.

# INSPECTION GUIDANCE

## Preparing for an Inspection

1. Call the assigned registrant and set up an inspection date (for best results, schedule the inspection a week or more in advance). If you would like to, you may use the call sheet that Jason developed (*see Jason to obtain a copy*). Notify the registrant that they will receive a self-audit form.

2. Gather the necessary inspection checklist, information notices, Wisconsin HSS 157 Employee Notice, radioactive material signs (Caution Radioactive Material and if needed Caution Radiation Area), radiation emergency phone number signs and if needed self-audits.

    - Inspection checklists are found on the shared radiation computer drive in the ***Agreement State Program folder*** under ***Inspection Checklist and Letters*** under ***Checklists***, then under their respective title (i.e., Portable Moisture/Density Gauges and XRF devices). They can also be found in the black filing cabinet in the cube along side Jason's cube (*Please copy the inspection checklist if you take the last one*).
    - Self-audits are found in the black file cabinet in the cube along side Jason's cube (*Please copy the self-audit if you happen to take the last self-audit*).
    - Information notices are found in the black file cabinet in the cube along side Jason's cube ( *Please copy the information notice if you take the last one*).
    - Wisconsin HSS 157 Employee Notices (the blue cards) are located on Jason's desk.
    - Radioactive signs (Caution Radioactive Material and if needed Caution Radiation Area) can be located on Mike's desk. So just ask Mike for a sign.
    - Radiation emergency phone number signs may be found on top of Mike's filing cabinet in his cube.

3. Obtain the original NARM folder from Linda and make a copy of the contents (See Jason if you have any questions). You should also ask Priscilla to print out the latest information on the registrant from the x-ray database. Place the copy in a newly created file folder with the registrant's name and registration number. Take the file folder along on the inspection (*Please do not take the original file out of the office*).

4. Obtain a survey instrument from storage location (B371) and check with Mike for availability (***Be sure to sign the survey instrument out***).

5. Be sure to take along your personal dosimeter and any other equipment needed, such as boots or a jacket.

6. Locate the location of the registrant's facility. Mapquest (www.mapquest.com) or Yahoo (www.yahoo.com) can be very helpful in obtaining maps to the registrant's location.

7. **REVIEW** - Inspection history, rules (the inspection checklist provides a good summary of the regulatory requirements), information notices, other similar registrant inspections, etc.

8. Perform the Inspection

## Finalizing the Inspection

Once you have completed the inspection;

1. Immediately inform Priscilla of completed inspection (date of inspection, registrant's name and registration number).

2. Return the survey instruments to the storage location (B371), and ***sign in survey meter***. Document manufacturer, model number, serial number and calibration date. Return unused forms, signs or postings back to their appropriate locations.

3. Electronically complete an inspection checklist and inspection letter.

   - Open the proper Inspection checklist as described in **Step 2, bullet 1,** in Preparing for an Inspection.

   - Click on **SAVE AS**

   - Open the **Agreement State File** Folder (You should be already in this folder, so therefore you may not be a need to open this folder). Upon opening this folder, open the folder entitled **Inspection Reports 2001.** Create a new file folder within this folder **(Inspection Reports 2001).** Contact Jason if you have question on creating a new file folder. Entitle the new file folder with the registration number of the registrant (ex. **XO 18745**). Click on OK. You will then need to open the new file folder you just created **(XO 18745).**

   - Click on the file name and title the document with the registrant's name followed by checklist, for example; SheboyganFoundry_Checklist.doc. Click on **Save,** you have now saved your checklist. You may now proceed to fill out the form electronically, be sure save your document frequently as you work on your inspection checklist.

- Open the proper inspection letter under their respective title (i.e., **Inspection Letter**) located under the **Inspection Checklist and Letters** under **Form Letters**, which is located under the **Agreement State Program** folder. Perform a SAVE AS. Save this document under new file folder you created in the **Inspection Reports 2001** folder (in our example it would be **XO 18745**). Title the document with the registrants name followed by letter; SheboyganFoundry_Letter.doc. You may now proceed to complete your inspection letter electronically. Be sure to save your document frequently as you work on inspection letter.

3. Print the inspection checklist and the inspection letter. Give the Materials Program Supervisor the inspection checklist, inspection letter and the file folder for review and signature. Give the signed letter, checklist and file folder to Priscilla to file, mail and update database (**The inspection letter needs to be completed and sent to the registrant 30 days after the inspection**). If for some reason Priscilla is out of the office you may send the letter to the registrant. If you do send the letter to the registrant be sure to put a copy of the checklist and inspection in the materials program folder. (*Place the materials program folder in the black filing cabinet by Jason's cube*). File an additional copy of the checklist and letter in the original x-ray file folder located in Room 150.

***Contact Jason if you have any question concerning the above information.***

# STATE OF WISCONSIN
# HEALTH AND FAMILY SERVICES

## Radiation Protection Section

**Radioactive Materials Program Procedure No. 3.03**
**Performance Based Inspection**

**Prepared By:**_____ **Date**_____
**Jason H. Hunt, Nuclear Engineer**

**Reviewed By:**_____ **Date** _____

**Cheryl K. Rogers, Materials Program Supervisor**

**Approved By:**_____ **Date**_____

**Paul Schmidt, Radiation Protection Section Chief**

**Effective Date:** _____

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## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure applies to the implementation of performance based inspections.

1.1.2 This procedure does not preclude the review of a licensee's program documentation.

1.1.3 This procedure applies to the observation of a licensee's program activities to determine if regulatory and technical objectives are being achieved.

1.1.4 This procedure helps the inspector to identify and prioritize those activities that impact on a licensee's performance.

### 1.2 References

1.2.1 USNRC, "Inspecting for Performance -Materials", Student Manual.

1.2.2 NRC Inspection Manual, Chapter 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States,' and Inspection of Agreement State Licensees Operating Under 10 CFR Part 150.20".

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

1.2.4 NRC Inspection Procedure 87103, "Inspection of Incidents at Nuclear Materials Facilities".

1.2.5 NRC Management Directive 8.10, "NRC Medical Event Assessment Program"

1.2.6 Chapter HFS 157, 'Radiation Protection,

1.2.7 Wisconsin Statute 254.31-254.45

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

The computer based "field notes" are located in:
L:EEP/Agreement State Program/Inspection Forms and Letters

### 1.4.1 Hardcopy Files

1.4.1 Current NRC Information Notices
1.4.2 Reading File
1.4.3 NRC Inspection Manual

## 1.5 Definitions

1.5.1 Core Inspection means all initial inspections of licensees and all routine inspections of priority 1, 2, and 3 licensees.

1.5.2 Initial Inspection means the first inspection after a license is issued.

1.5.3 Inspection means the act of assessing licensee performance to determine if radioactive materials are used safely; and, whether the licensee is in compliance with rules, regulations, statutes, license conditions, and the licensee commitments submitted in support of the application for license and incorporated in the license by "tie-down" conditions. Inspections include a visit to a licensee's facility and/or job site, observation of licensed activities, interaction with licensee personnel, and reporting of the inspection findings. Pre-licensing visits or telephone communications are not inspections.

1.5.4 Performance Based Inspection (PBI) means observation of a licensee's program activities to determine if regulatory and radiation safety objectives are being achieved. This type of inspection can be applied to any functional area of any license. The only variable is the technical nature of the activities of different licensees. The principal measures of successful performance are safety and reliability. A performance-based inspection focuses on the safety and reliability of program activities.

1.5.5 Safety means relative freedom from harm or hazard to the public, workers, or the environment. Safety is a relative measure of the hazard associated with a given activity. Inspectors need not be able to quantify levels of safety during an inspection. It is sufficient to identify whether or not an activity, condition, or trend is adverse to safety. Safety must not be dependent on any administrative classification system.

1.5.6 Reliability means the capability to perform as designed or intended when needed and for the duration required. A lack of reliability is generally only of concern when safety is adversely affected as a result. It is important for inspectors to recognize that reliability applies to both equipment and workers.

1.5. 7 Acute Performance Conditions means conditions that have an obvious adverse impact on safety and/or reliability.

1.5.8 Latent Performance Conditions means conditions that are underlying and usually obscure. If unchanged, these may result in acute conditions at some future time if circumstances change.

1.5.9 Precursor Performance Conditions means conditions that are changing with time and will likely result in acute conditions at some future time. Precursors are similar to latent conditions, but are more definite in their eventual outcome.

1.5.10 Risk means the relationship between consequence and probability. The highest probability coupled with the most severe consequence represents the highest risk.

1.5.11 Non-Core Inspections means routine inspections of priority 5 licensees, other than initial inspections.

1.5.12 Reactive Inspections means a special inspection in response to an incident, allegation, or special information obtained by the department, e.g., misadministration reports. These inspections may focus on one or several issues and need not examine the rest of a licensee's program. If all of the activities normally reviewed during a routine inspection are not reviewed then the requirement to inspect the facility at an established frequency is not satisfied.

1.5.13 Routine Inspection means a periodic, comprehensive inspection performed at a specified frequency.

1.5.14 Special Inspection means those inspection activities where special guidance is needed. These activities include: (1) inspections of expired licenses, terminated licenses, and licenses undergoing decommissioning; (2) inspections of significantly expanded programs; (3) reciprocity inspections; (4) temporary job site or field site inspections; (5) team inspections; (6) inspections of abandoned licenses; and (7) general licensee's program inspections.

1.5.15 Team Inspections means inspections conducted by two or more inspectors or any inspection that includes an inspector from outside of WI (other than IMPEP or supervisory accompaniments). A team inspection can be a routine inspection of a major licensee or a reactive inspection in response to a particular incident or event. Team inspections don't include those where a supervisor accompanies an inspector in order to evaluate the inspector's performance.

1.5.16 Telephone Contact means contacts by telephone and documented in the license file, to determine the status of a licensee's activities, to assess compliance or to exchange information with the licensee. Telephone contacts are not considered to be inspections.

## 2.0 RESPONSIBILITIES

### 2.1 Program Assistant

- Maintains the hardcopy file with current inspection field notes/reports and the computer based letters, forms and reports files.
- Updates files as necessary.
- For initial inspections, report all the following information to the materials program supervisor: the licensee, the license number and priority, the date the license was issued, the date the licensee received licensed material, the date licensed activity started, and when known, the date when the initial inspection must be conduct.

## 2.2 Nuclear Engineer

For each assigned initial, routine core and non-core inspection:

- Reviews, as appropriate, application, license and inspection files, NRC Information Notices, and Regulatory Guides (WISREGS) and prepare an inspection plan.
- Determines instruments needed to conduct independent measurements.
- Conducts a performance-based inspection following review and approval of the inspection plan by the Materials Program Supervisor, or designee.
- Reviews the inspection findings with the Materials Program Supervisor at the conclusion of the inspection.

For each assigned reactive or special inspection:

- Reviews the required scope of the inspection with the Materials Program Supervisor, or designee, and prepares an inspection plan for review and approval.
- Conducts an inspection based on the approved inspection plan. Reviews the inspection findings with the Materials Program Supervisor at the conclusion of the inspection.
- Informs the Materials Program Supervisor as to changes/progress in accomplishing assigned inspections.

The Nuclear Engineer shall inform the licensee of pending initial, special and with the exception of allegations, reactive inspections.

## 2.3 Materials Program Supervisor (MPS)

- Reviews and approves inspection plans.
- Reviews the inspection findings with the assigned inspector(s) at the conclusion of the inspection.
- Determines if a reactive or special inspection is warranted, if it should be performed promptly or if it can be included in the next routine inspection. Assigns an inspector or team of inspectors to perform the inspection. Reviews the inspection findings with the assigned inspector(s) at the conclusion of the inspection.
- Reports inspection statistics to the Radiation Protection Section Chief 3.0

## 3.0 PROCEDURE

### 3.1 Inspection Schedule

The required frequencies for all priorities of licenses, reactive and special inspections are defined in Sections 3.3 through 3.7 of RMPP No. 3.01, "Scheduling of Inspections".

3.1.1 Core Inspections

For initial inspections, the licensee is required to report the first receipt of licensed material to the Materials Program Supervisor. The license shall be inspected within 6 months of the receipt of licensed material, within 6 months of beginning licensed activity, or within 1 year of license issuance, which ever is first. Initial inspections shall be announced.

For routine inspections of priority 1,2 or 3 licenses the specified due date shall be reported to the Materials Program Supervisor (For example, a priority 1 license with an inspection due date of 7/1/03 shall be conducted any time during the period from 4/1/03 to 10/1/03). Routine core inspections shall be unannounced.

3 .1.2 Non-Core Inspections

For routine inspections of priority 5 licenses the specified due date and the inspection window dates (+/- 1.25 year) shall be reported. Priority 5 inspections shall be unannounced.

3.1.3 Reactive and Special Inspections

Inspection frequencies for reactive and special inspections are defined in Section 3.6 and 3.7 of RMPP No. 3.01 "Scheduling of Inspections".

3.1.4 Extension and Reduction of Inspection Frequency

Inspections frequencies for licenses that have had the frequencies extended or reduced are discussed in Sections 3.4 and 3.5 of RMPP No. 3.01 "Scheduling of Inspections".

## 3.2 Inspection Preparation

Preparation for inspections is defined in RMPP No. 3.02, "Inspection Preparation".

Attachment No. 3.03-1 is an example of an inspection plan.

## 3.3 Performance Based Inspections

### 3.3.1 Entrance Meeting

The inspection begins with a meeting with appropriate licensee personnel. The inspector shall assure that licensee management (signer of the application for license or appropriate senior management) will be made aware of the inspection. If appropriate, the exit meeting should be scheduled during the entrance meeting.

### 3.3.2 The Inspection

Observations of licensee operations, interviews with the staff, document review to complement and support observations, and radiation surveys to obtain independent and confirmatory measurements should be conducted.

Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety. The performance based inspection process represents a change in sequence from the more traditional programmatic inspections. In contrast a records based inspection emphasizes programs, facilities or procedural controls to be verified initially. In performance based inspections a problem with licensee performance leads the inspector to identify programs or procedures for evaluation.

Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of records should occur only if the current records are out of compliance and it is necessary to determine the presence of a prevalent or persistent problem.

At the completion of the inspection and prior to the exit interview the Performance Evaluation Factors (PEF) Checklist (Attachment RMPP No. 3.03-2) shall be reviewed. The checklist may be used by the inspector as a reminder of the inspection findings.

### 3.3.3 Exit Interview

The inspection concludes with an exit meeting with licensee management. When an activity results in significant problems, licensee management should be informed as soon as possible. This will allow the licensee sufficient time to begin root cause analysis and possibly determine a corrective action prior to termination of the inspection.

### 3.3.4 Evaluating Inspection Results

After returning from an inspection trip, the inspector shall discuss the results of the inspection trip with the Materials Program Supervisor. The inspector should strive to make an accurate determination of the actual condition of the activities inspected. The technical basis of identified problems must be emphasized, not just the symptoms or administrative indications. The reliability of both equipment and workers should be evaluated with respect to safety. Inspection findings should be evaluated for generic health and safety problems. Performance conditions should also be evaluated to predict their impact on future operations. This meeting need not be documented.

## 3.4 Reactive & Special Inspections

### 3.4.1 Incidents

Inspections of reportable incidents (e.g., medical events, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program.

The emphasis during the reactive inspection will be on the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes and to the formulation of corrective actions to prevent recurrence.

Issues of compliance will generally be addressed after all safety issues and program weaknesses are identified and understood.

With the exception of medical events, all other reactive inspections will be performed using the guidance in NRC Inspection Procedure (IP) 87103, "Inspection of Incidents at Nuclear Materials Facilities".

### 3.4.2 Medical Events

Inspections of medical events shall be conducted in accordance with the guidance in NRC Management Directive 8.10, "NRC Medical Event Assessment Program"

### 3.4.5 Allegations

Allegations shall be processed in accordance with RMPP No. 4.01, "Management of Allegations".

## 4.0 RECORDS

### 4.1 Hardcopy

4.1.1 Letter with Notice of Violation or Clear Inspection Letter or WI Form-591
4.1.2 Inspection Field Notes/Inspection Report maintained in File

### 4.2 Computer Based

4.2.1 Computer based field notes.

## 5.0 ATTACHMENTS to RMPP No. 3.03

RMPP No. 3.03-1 "Sample of a Performance Based Inspection Plan"
RMPP No. 3.03-2 "Performance Evaluation Factor Checklist"

# Radioactive Materials Program
# Guidelines for Completing an Inspection Plan

## DIRECTIONS

The following information is provided to be a help in completing the questions in the inspection plan and preparing for the inspection.

## DEFINITIONS

**AREA:** The licensee's organizational component

**Examples** Industrial radiography – field operations; Nuclear Pharmacy Operations; Radio-pharmaceutical therapy; or Radiation Therapy

**ACTIVITY:** Task performed by individuals within an area

**Examples** Industrial radiography surveys; Milking the Generator; Administration of I-131; or Gamma Knife patient treatment

**ELEMENT:** Observable aspects of an activity

**Examples** Surveys of camera after source crank-in; Use of: shielded container, time, gloves, syringe shield, survey meter

## LICENSEE ACTIVITY SLECTION GUIDELINES

a. Identify high priority areas and activities

b. Activities in progress are preferred

c. Identify medium and low priority activities that can be inspected concurrently

d. Give preference to high priority elements

## INSPECTION METHOD

Preferred Method: Direct Observation

Acceptable alternatives:
a. Interview selected licensee personnel
b. Review of activity documents
c. Walk-through or demonstration

***A, and B. together are acceptable but time consuming, drills should not be performed without careful planning.***

***Complete the Inspection Plan located on the Backside***

# Radioactive Materials Program
# Inspection Plan

| Licensee Information | |
|---|---|
| License Number | **Licensee Contact:** (Name and Telephone Number) |
| **Licensee** (Name and Address) | |

| License and Inspection Information | | | |
|---|---|---|---|
| **Last Amendment No.** | Date of Amendment | | |
| Priority | Category *s. HFS 157.10(3)* | | |
| Date of Last Inspection | Proposed Date of this Inspection | | |
| Type of Inspection | ☐ Announced | ☐ Initial | ☐ Special |
| | ☐ Unannounced | ☐ Routine | ☐ Re-inspection |

**Performance Based Inspection Plan** *Attach Additional Sheets if Necessary*

1. **Briefly identify the higher priority areas and activities to be reviewed and lower priority areas that may be reviewed concurrently.**

2. **Briefly indicate the major elements to be observed. List individuals/positions to be interviewed.**

3. **Briefly list the documents to be reviewed when preparing for the inspection (ex. License conditions, license, Wisconsin Rule, WISREGS).**

4. **List and explain what survey meter(s) will be used on the inspection.**

| *Lead Inspector Signature* | *Date* | *Materials Program Supervisor Signature* | *Date* |
|---|---|---|---|

# PERFORMANCE EVALUATION CHECKLIST

| | | | |
|---|---|---|---|
| **License Number:** | | **Licensee (Name and Address)** | |
| **Inspection Date:** | | | |

## Performance Factors

| | | |
|---|---|---|
| a. Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight. | ☐ Yes | ☐ No |
| b. RSO too busy with other assignments | ☐ Yes | ☐ No |
| c. Insufficient Training | ☐ Yes | ☐ No |
| d. Radiation Safety Committee fails to meet or function inadequately | ☐ Yes | ☐ No |
| e. Inadequate consulting services or inadequate audits | ☐ Yes | ☐ No |

**Remarks** (consider above assessment and/or other pertinent Performance Evaluation Factors (PEFs):

## Other Pertinent PEFs

- User not familiar with safety procedures of license conditions
- Excessive missed surveillance
- Lack of audits
- RSO not separated from responsibility for production activities
- Repeated failure to correct violations identified by consultant or licensee
- Failure to implement adequate corrective actions on pervious violations
- Inability to readily retrieve records and documentation pertaining to licensed program
- Reportable events/medical events since last inspection
- Numerous repeat violations
- Numerous medical events
- Financial instability of licensee
- Frequent resignation of staff
- Inability to perform all required surveys on time
- Lack of training documentation
- Failure to assess the performance of personnel training
- Allegations made since last inspection
- Licensee not inventorying radioactive material
- Lack of structure to identify staff responsibilities
- Company subject to name change, developed into a subsidiary, or transferred
- Failure to provide training to individuals before authorizing them to use radioactive material
- Failure to retain authorized users
- Inadequate RSO attention to radiation safety program
- Incomplete responses to previously identified violations
- No evidence of licensee capable of responding to a radiological event
- Inadequate surveys
- RSO spends insufficient time at facility
- Identified violations similar to those previously identified

# STATE OF WISCONSIN
# HEALTH AND FAMILY SERVICES

## Radiation Protection Section

**Radioactive Materials Program Procedure No. 3.04**

**Documentation of Inspection Results**

**Prepared By:**_____ **Date**_____
**Paul J. Caleb, Nuclear Engineer**

**Reviewed By:**_____ **Date**_____
**Cheryl K. Rogers, Materials Program Supervisor**

**Approved By:**_____ **Date**_____
**Paul S. Schmidt, Chief**

**Effective Date**_____

## Table of Contents

## Documentation of Inspection Results

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure is designed to ensure that reports of inspections clearly communicate significant inspection results to licensees, staff, and the public.

1.1.2 This procedure will ensure that reports of inspections provide conclusions about the effectiveness of the program(s) and/or activities inspected. The depth and scope of the documented conclusions should be commensurate with the depth and scope of the inspection.

1.1.3 This procedure will provide a basis for enforcement action.

### 1.2 References

1.2.1 NRC Inspection Manual, Chapter 0610, "Inspection Reports", (Selected parts applicable to the materials program).

1.2.2 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program".

1.2.3 Chapter HFS 157 'Radiation Protection"

1.2.4 WI Stats. 254.31-.45

1.2.5 NRC Enforcement Manual, Section 4.3

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

Inspection Checklists and Letters

- Inspection Checklist and Letters can be found in L: Agreement State Program/Inspection Checklist and Letters

- For detailed instructions how to access and save Inspection Checklist and Letters see – 'Inspection Guidance' Attachment 3.02-1

## 1.4 Hardcopy Files

## 1.5 Definitions

1.5.1 Apparent Violation means a potential noncompliance with a regulatory requirement that has not yet been formally cited as a violation in a Notice of Violation or order.

1.5.2 Closed Item means a matter previously reported as a noncompliance, an unresolved item, or an inspection follow-up item that the inspector concludes has been satisfactorily resolved, based on information obtained during the current inspection.

1.5.3 Deviation means a licensee's failure to satisfy a non-legally binding commitment (e.g. failure to tie-down a commitment during licensing and the licensee has not implemented that commitment).

1.5.4 DHFS Record means any written, electronic, or photographic record under legal DHFS control that documents the policy or activities of the DHFS or a DHFS licensee.

1.5.5 Draft Inspection Report means any version of the inspection report before its official issuance.

1.5.6 Escalated Enforcement Action means a Notice of Violation for any Severity Level I, II, or III violation, or a civil penalty, or order based on a violation.

1.5.7 Finding means an observation that has been placed in context and assessed for significance.

1.5.8 Inspection means the examination and assessment of any licensee activity to determine its effectiveness, to ensure safety and to determine compliance.

1.5.9 Inspection Document means any material obtained or developed during an inspection that is considered to be a DHFS record.

1.5.10 Inspection Follow-Up Item means a matter that requires further inspection because of a potential problem, because specific licensee or DHFS action is pending, or because additional information is needed that was not available at the time of the inspection.

1.5.11 Minor Violation means a Severity Level IV or V violation.

1.5.12 Non-Cited Violation (NCV) means a violation for which the staff chooses to exercise discretion and refrain from issuing a Notice of Violation.

1.5.13 Noncompliance means a violation, non-cited violation, or deviation.

1.5.14 Notice of Violation (NOV) means a formal written citation in accordance with HFS 157 subchapter XII that sets forth one or more violations of a legally binding regulatory requirement.

1.5.15 Observation means a fact, or any detail noted during an inspection.

1.5.16 Open Item means a matter that requires further inspection. The reason for

requiring further inspection may be that the matter has been identified as a noncompliance, unresolved item, or inspector follow-up item.

1.5.17 Potentially Generic Issue means an inspection finding that may have implications for other licensees, certificate holders, or vendors whose facilities or activities are of the same or similar manufacture or style.

1.5.18 Regulatory Commitment means an explicit statement to take a specific action, agreed to or volunteered by a licensee, where the statement has been submitted in writing to the DHFS.

1.5.19 Recommendation means an issue or area of concern with insufficient documentation to issue a violation.

1.5.20 Requirement means a legally binding obligation such as a statute, regulation, license condition, or order.

1.5.21 Unresolved Item means a matter about which more information is required to determine whether the issue in question is an acceptable item, a deviation, or a violation.

1.5.22 Vendor means a supplier of products or services to be used in a DHFS licensed facility or activity. The vendor may be an NRC, Agreement State or DHFS licensee or the vendor's product may be required to have an NRC Certificate of Compliance (e.g., certain transport packages such as waste casks or radiography devices)

1.5.23 Violation means the failure to comply with a legally binding regulatory requirement such as a statute, regulation, order, or license condition.

1.5.23 Willfulness means an attitude toward compliance with requirements that ranges from the careless disregard for requirements to a deliberate intent to violate or to falsify.

## 2.0 RESPONSIBILITIES

### 2.1 Program Assistant

- Maintains the hardcopy files and the computer based letters, forms and report files.
- Tracks the inspection documentation once informed by the nuclear engineers that the inspection has been completed.
- Updates the inspection history form.

### 2.2 Nuclear Engineer

- Discusses inspection findings and recommended enforcement action with the Materials Program Supervisor as soon as possible following completion of the inspection.
- Completes field notes or prepares a narrative report, based on the results of the inspection.
- Prepares a RMP inspection findings transmittal letter with or without a NOV

depending on the results of the inspection, and providing that an WI Form 591 was not issued at the conclusion of the inspection.

- The nuclear engineer may sign the inspection findings transmittal letter once the Supervisor signs the inspection report.

### 2.3 Materials Program Supervisor (MPS)

- Concurs with the inspectors findings and recommendations or prescribes alternative actions
- Reviews and approves the field notes or narrative report of the inspection findings.
- Reviews and approves the RMP inspections findings transmittal letter and the NOV.

## 3.0 PROCEDURE

### 3.1 Methods of Documenting Inspection Results

Inspections shall be documented by completing field notes or a narrative report.

### 3.2 WI Form 591

- "Safety Inspection" shall be used:
  (a) to document clear inspections and inspections resulting in Severity Level IV or V violations that are neither willful nor repetitive and that can be corrected while the inspector is present, or that the licensee agrees to correct.
  (b) to document non-cited violations (NCV). (See Section 4.3 of the NRC Enforcement Manual)

- When the WI Form 591 is used to document the results of an inspection, the inspector must ensure that for each cited or non-cited violation, the form includes a brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met and the reference to the regulation or license condition that was violated.

- The inspector must ensure that the inspections findings are documented in the field notes in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement and when it was violated.

Corrective action provided by the licensee during the inspection should also be included in the field notes.

For NCVs, the field notes should document why the violation was not cited and what corrective action was taken or planned by the licensee

Attachment 3.05-1 is an example of an WI Form 591.
Attachment 3.05-2 lists examples of violations that may be cited on a WI Form 591.

NOTE: Procedure 3.05 is Enforcement, Escalated Enforcement and Administrative Actions

### 3.3 Field Notes/ Inspection Checklist

Field notes are usually typed but this is not a requirement, shall be legible and shall contain:

(a) sufficient detail to describe the inspection that was conducted including operations observed to document the performance based part of the inspection;
(b) the compliance status of topics examined during the inspection;
(c) the status of follow-up items involving prior enforcement or reported licensee events;
(d) sufficient information to support violation findings;
(e) description of completed or anticipated corrective actions to any identified NCV's, minor violations cited in WI Form 591; and
(f) sufficient detail for management, license reviewers, and other inspectors to evaluate the licensee's overall safety program.

Field notes must document routine inspection activities that are not covered in a narrative report.

A different inspector should be able to use the field notes in preparing for a subsequent inspection, and to determine whether corrective actions have been taken.

Field notes should be completed within 5 working days following the completion of the on-site portion of the inspection.

### 3.4 Narrative Report

A narrative inspection report is required for reactive inspections and for team inspections involving agencies outside of WI (other than representatives of NRC's Office of Agreement States Programs) and for inspections that result in an

enforcement conference or escalated enforcement.

For escalated cases, the narrative report should address all areas covered in the inspection.

For medical events the narrative report should follow the guidance in NRC Management Guidance 8.10.

For allegations the narrative report should follow the guidance in RMPP No. 4.01 "Management of Allegations".

Narrative reports should be completed within 21 working days of the completion of the on-site portion of the inspection.

### 3.5 Inspection Report Transmittal Letter and NOV

The Inspection Report transmittal letter and the NOV, if required, shall be sent within 30 days of completion of the inspection if a WI Form 591 has not been issued.

Standard enforcement paragraphs should used in the NOV.

## 4.0 RECORDS

### 4.1 Hardcopy

4.1.1 Inspection reports and inspection transmittal letters in licensee's file.
4.1.2 Inspection History Form documents the licensee's history for an overview of a licensee's historical performance.

### 4,2 Computer Based

4.2.1 Reports generated to support the tracking of the inspections performed.
4.2.2 Standard enforcement paragraphs to document noncompliance items are located in –L: Agreement State Program\Standard Paragraphs

## 5.0 ATTACHMENTS

**None**

# STATE OF WISCONSIN
# HEALTH AND FAMILY SERVICES

## Radiation Protection Section

**Radioactive Materials Program Procedure No. 3.05**

**Enforcement, Escalated Enforcement and Administrative Actions**

**Prepared By:**_____**Date**_____
**Dan Stefenel**

**Reviewed By:**_____**Date**_____
**Cheryl K. Rogers, Materials Program Supervisor**

**Approved By:**_____**Date**_____
**Paul Schmidt, Radiation Protection Section Chief**

**Effective Date:**_____

## 1.0 GENERAL INFORMATION

### 1.1 Purpose

The purpose of the DHFS Radioactive Materials Program is to support the overall safety mission of protecting the public health and safety, and the environment through appropriate enforcement actions.

### 1.2 Applicability

Enforcement action should be implemented:

- As a deterrent to emphasize the importance of regulatory compliance, and
- To encourage prompt identification and comprehensive corrective action following the occurrence of violations.

Enforcement actions are dependent upon the circumstances of each individual case of violation. The implementation of specific enforcement actions requires the exercise of discretion after consideration of all available alternatives. However, under no circumstances, will licensees unable or unwilling to achieve and maintain adequate levels of safety be permitted to conduct licensed activities.

### 1.3 Statutory Authority

Statutory authority for promulgation and implementation of enforcement procedures is contained in the following:

- Wisconsin Statutes, Chapter 254, Subchapter III, Paragraphs 254.33, 254.34, 254.365, 254.37, 254.38, and 254.45, and
- HFS 157, Subchapter XII, Section 157.90

### 1.4 References

- NUREG-1600, *General Statement of Policy and Procedures for NRC Enforcement Action-Enforcement Policy.*
- Wisconsin Statutes, Chapter 254: Environmental Health, Subchapter III: Radiation Protection.
- HFS 157, Subchapter XII: Enforcement, Section 157.90.
- HFS157.05(2)

### 1.5 Documentation Requirements

Any enforcement correspondence to or from a licensee shall be placed in the Radioactive Material License file.

## 1.6 Definitions

1.6.1 Administrative Action: action implemented in addition to formal enforcement actions to supplement the enforcement program.

1.6.2 Aggregation of Violations: group of violations that may be evaluated in the aggregate, providing the violations have the same underlying cause, resulting in a violation of a higher severity level. For example, a group of Severity Level 4 violations may be evaluated in the aggregate and result in a Severity Level 3 violation, or a group of Minor Violations if evaluated in the aggregate may result in a Severity Level 4 violation. Severity Level 2 and 3 violations are normally not aggregated.

1.6.3 Department: the department of health and family services

1.6.4 Discretion: the State's authority to either escalate or mitigate enforcement sanctions to ensure that the resultant enforcement action appropriately reflects the level of the State's concern regarding the violation at issue and conveys the appropriate message to the licensee.

1.6.5 Enforcement Action: a Notice of Violation based on violation(s) of a license requirement.

1.6.6 Escalated Enforcement Action: a forfeiture for any Severity Level 1, 2, or 3 violation(s) or an order based on violation(s) of a requirement.

1.6.7 Forfeiture: any monetary penalty, but excluding criminal penalties, levied on a person, licensee, or registrant because of violations of statutes, rules, conditions , or registrations

1.6.8 Licensee Official: a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on the license.

1.6.9 Notice of Violation (NOV): a written notice provided to a licensee in response to an alleged violation of the Act, Chapter HFS 157, the conditions of a license, or an order issued by the department.

1.6.10 Order: a written directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take other appropriate action. Orders may be issued in lieu of, or in addition to, forfeitures, as appropriate for Severity Level 1, 2, or 3 violations.

1.6.11 Predecisional Enforcement Conference: a meeting between the Radiation Protection Section (RPS) and the licensee that may be called whenever the

RPS becomes aware of potential violation(s) which potentially warrant escalated enforcement action. The purpose of the conference is to allow the RPS to obtain additional information necessary for determination of potential enforcement action.

1.6.12 Repetitive Violation: a violation that could have been prevented by a licensee's action to correct a previous violation occurring either (1) within the past two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer.

1.6.13 Requirement: a legally binding requirement such as a statute, rule, license, or order.

1.6.14 Severity Level: categorization of violations of license requirements based on the seriousness of the violation. One of five levels of severity is assigned to a violation, ranging from Severity Level 1, signifying the most significant, to Severity Level 5 the least. See ch. HFS 157.90(1) for definitions and ch. HFS 157, Appendix R, for examples of each severity level.

1.6.15 Willfulness: a characteristic of a licensee's actions whereby violations result from deliberate intent to falsify documentation pertaining to license requirements, to violate license requirements, or from careless disregard for license requirements.

## 2.0 RESPONSIBILITIES

### 2.1 Program Assistant

The program assistant is responsible for maintenance and distribution of all required documentation relating to the regulation of licensee activities, and any other activities as assigned by the Materials Program Supervisor. The program assistant reports to the Materials Program Supervisor.

### 2.2 Staff Inspection Personnel

The staff inspection personnel are responsible for conducting licensee inspections and reactive (investigative) inspections in accordance with applicable procedures, rules, and instructions; for categorizing and documenting any apparent violations of license conditions observed during the inspections; and for reporting these apparent violations to the Materials Program Supervisor. Staff inspection personnel report to the Materials Program Supervisor.

### 2.3 Materials Program Supervisor

The Materials Program Supervisor is responsible for reviewing inspection and reactive (investigative) inspection findings; for approving the issuance of any proposed NOVs; for determining if the threat to health and safety described in any NOVs warrants the prompt issuance of an order; for determining whether a

- delineates other action against the licensee as deemed appropriate by the department.

- RPS may issue orders without prior opportunity for hearing.

- Orders are effective immediately whenever it is determined that the public health, interest, or safety so requires, or when the order is in response to a violation involving willfulness.

- Types of orders:

  - License Modification Orders: requires change to licensee equipment, procedures, personnel, or management controls as deemed necessary.

  - Suspension Orders: requires suspension of all or part of the licensed activity. Normally, a licensed activity is not suspended nor is suspension prolonged for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken or planned. Suspension orders are used:

    1) to remove a threat to public health and safety, security, or the environment

    2) when the licensee has not adequately responded to other enforcement action

    3) when the licensee interferes with the conduct of an inspection or investigation

    4) for any reason not addressed above for which suspension of license activity is legally authorized.

  - Revocation Orders: revokes the license authorizing us of radioactive materials when:

    1) a licensee is unable or unwilling to comply with license requirements,

    2) a licensee refuses to correct a violation,

    3) a licensee does not respond when required by an issued NOV,

    4) a licensee refuses to pay an applicable fee under the department's rules, or

    5) any condition exists which would warrant refusal of a license on an original application.

predecisional enforcement conference is warranted; for making recommendations pertaining to the exercise of discretion in any proposed enforcement action; for recommending to the Chief, Radiation Protection Section if legal assistance is required; and for forwarding, as appropriate, any enforcement recommendations to the Chief, Radiation Protection Section. The Materials Program Supervisor reports to the Chief, Radiation Protection Section.

### 2.4 Chief, Radiation Protection Section

The Chief of the Radiation Protection Section is responsible for reviewing recommendations forwarded from the Materials Program Supervisor and, as appropriate, either approving, modifying, or disapproving the recommendation for assessment and issuance of forfeiture or issuance of an order or both. The Chief of the Radiation Protection Section, or higher level manager, is responsible for the actual issuance of an escalated enforcement action. The Chief of the Radiation Protection Section is also responsible for responding, as necessary, to a request for hearing by a licensee made in accordance with HFS 157.90(3). In the event of licensee failure to pay an imposed forfeiture, the Chief of the Radiation Protection Section is responsible for requesting enforcement assistance in accordance with Wisconsin Statutes, Chapter 254.45 (5).

## 3.0 ENFORCEMENT ACTIONS

### 3.1 Notice of Violation

- The issuance of a NOV to a licensee following an inspection is the usual method of formally documenting violations and is normally the only enforcement action taken unless the criteria for escalated enforcement are met.

- The recipient of a NOV is required to respond with a written statement describing the following:

  - Any corrective actions taken and results achieved

  - Any corrective actions planned to prevent recurrence

  - The date when full compliance is expected.

- All or portions of a written response may be waived if relevant information was previously provided in writing by the licensee or documented in the inspection report.

- A revised NOV shall be issued if the determination is made that the violations will result in an escalated enforcement action.

### 3.2 Predecisional Conference

A predecisional conference may be convened prior to implementation of an escalated enforcement action if considered warranted by the RPS. The purpose of this conference shall be to gather further information from the licensee. This conference shall accomplish, at the least, a mutual understanding between the licensee and the department of:

- facts, root causes and missed opportunities associated with the apparent violations
- any prior corrective actions taken or planned
- the significance of the issues and the need for lasting comprehensive corrective action.

### 3.3 Forfeiture

- A forfeiture is a monetary penalty intended to deter future violations, and to emphasize the need for licensees to identify and report violations and to take prompt comprehensive corrective action.
- Assessment of a forfeiture includes four decisional factors:
  1) The imposition on the licensee of any escalated enforcement action within the last two years or last two inspections, whichever is longer
  2) Any credit merited to the licensee for identification
  3) Any licensee corrective action taken or planned related to the identification
  4) Whether, in view of all circumstances surrounding the violation, the exercise of discretion is warranted.
- The lack of licensee management involvement in the violation shall not be used to mitigate a forfeiture, although direct or indirect licensee management involvement may lead to an increase in the amount of forfeiture imposed.
- The RPS has the option of discretion in easing of enforcement, but only if the RPS is adequately satisfied that such discretion will not adversely affect health and safety.
- Forfeitures shall be assessed and issued in accordance with HFS157.90(2).

### 3.4 Orders

- An order is a written department directive that:
  - modifies, suspends, or revokes a license,
  - directs a licensee to cease and desist from a given practice or activity, or

- Cease and Desist Orders: cease and desist orders require a person to stop an unauthorized activity that has continued following notification by the department that the activity is unauthorized.

- Emergency Orders: issued when immediate action is required to protect public health and safety, and may be issued without notice or hearing. The order shall describe the existence of an emergency and the action required, including sequestration or impoundment of the radioactive source, to mitigate the emergency.

- Orders to unlicensed persons: issued to unlicensed persons, including vendors and contractors and their employees, when deliberate misconduct has been identified that potentially violates department requirements, when incomplete or inaccurate information is deliberately submitted, or when the department loses reasonable assurance that the regulated person will meet department requirements if the unlicensed person continues involvement in activities covered by license, rule, or registration.

- Orders shall be issued in accordance with s. HFS 157.91(2) or s. HFS 157.91(4), as applicable.

## 3.5 Administrative actions

### 3.5.1 Confirmatory Action Letter (CAL)

- A CAL, issued immediately following an inspection, is a letter confirming a licensee's verbal agreement to take the necessary actions to correct significant concerns regarding health and safety, safeguards, or the environment.

- Issuance of a CAL requires the concurrence of the Materials Program Supervisor and the Chief of the Radiation Protection Section and may replace the issuance of a NOV.

- Issuance of a CAL does not preclude the implementation of an escalated enforcement action, if deemed warranted by the department.

### 3.5.2 Notice of Deviation

- A Notice of Deviation is a notice issued to a licensee describing the licensee's failure to satisfy a non-legally binding commitment.

- A Notice of Deviation requests a written statement from the licensee describing corrective actions taken or planned, the results achieved, and date when planned corrective actions will be completed.

### 3.5.3 Demand for Information

A written demand for information is issued to a licensee to enable the department to determine whether an order or other escalated enforcement action is warranted.

3.5.4 Form 591: [*title*]

- A Form 591 is issued at the conclusion of an inspection to document a clear inspection or an inspection resulting in Severity Level 4 or Level 5 violations or both that are neither willful nor repetitive and were corrected while the inspector was present or the licensee committed in writing to correct the violation(s) within 30 days

- Attachment 4.2 lists violations that may be cited on Form 591.

- No written response is required.

3.5.5 Inspection Letter

- An inspection letter may be issued in lieu of Form 591 to document a clear inspection or an inspection resulting in Severity Level 4 or Level 5 violations or both that are neither willful nor repetitive and that were corrected while the inspector was present or the licensee committed in writing to correct within 30 days.

- Attachment 4.2 lists violations that may be cited on an inspection letter.

- No written response is required.

## 4.0 ENFORCEMENT PROCEDURE

### 4.1 Disposition of Inspection Findings

4.1.1 Upon conclusion of an inspection, staff inspection personnel shall review the preliminary findings and determine which of the following were observed:

- No violations
- Any Severity Level 4 or 5 violations—not willful or repetitive
- Any Severity Level 5 violations—willful and/or repetitive
- Any Severity Level 4 violations—willful and/or repetitive
- Any Severity Level 3 violations
- Any Severity Level 2 violations
- Any Severity Level 1 violations
- Any Severity Level 1, 2, 3—willful and/or repetitive

NOTE: In determining the severity level of a violation involving willfulness, consideration should be given to the position and responsibilities of the person(s) involved, the significance of the underlying violation, the intent of the violator(s), and any economic advantage gained. If the licensee refuses to correct a minor violation in a

reasonable time such that it willfully continues, then the resulting violation should be assigned to at least Severity Level 4.

4.1.2 If inspection findings result in **No violations** or **any Severity Level 4 or 5 violations (not willful or repetitive)**, then inspection personnel shall issue to the licensee:

- A Form 591 if a response is required
- An Inspection Letter if no response is required.

4.1.3 If inspection findings result in **any Severity Level 5 violations (repetitive)**, then inspection personnel shall upgrade the violation to Severity Level 4 and issue a NOV to the licensee. If inspection findings result in **any Severity Level 5 violations (willful)**, then inspection personnel shall refer the finding to the Materials Program Supervisor for review and possible escalation to Severity Level 3 for determination of the need for escalated enforcement action.

4.1.4 If inspection findings result in **any Severity Level 4 violations (repetitive)**, then inspection personnel shall upgrade the violation to Severity level 3 and issue a NOV to the licensee. If inspection findings result in **any Severity Level 4 violations (willful or repetitive or both)**, then inspection personnel shall refer the finding to the Materials Program Supervisor for review and determination of the need for prompt escalated enforcement action.

4.1.5 If inspection findings result in **any Severity Level 3 violations**, then inspection personnel shall refer the finding to the Materials Program Supervisor for review and determination of whether a NOV or an escalated enforcement action is warranted.

4.1.6 If inspection findings result in **any Severity Level 2, Severity Level 1, or Severity Level 1, 2, and/or 3—willful and/or repetitive**, then inspection personnel shall immediately refer the findings to the Materials Program Supervisor. The Materials Program Supervisor shall confer with the Chief of the Radiation Protection Section for determination of the need for and the extent of escalated enforcement action, and whether a predecisional enforcement conference is warranted.

## 4.2 Emergency Orders

If, during the course of an inspection or during review of inspection findings, an emergency affecting public health and safety or the environment is determined to exist, then the department shall immediately issue an order to sequester or impound the licensed radiation source(s) as necessary to mitigate the emergency.

## 5.0 ATTACHMENTS

5.1 Attachment 3.05-1 WI Form 591

5.2 Attachment 3.05-2 Examples of violations that may be cited on a WI Form 591

DEPARTMENT OF HEALTH AND FAMILY SERVICES
Division of Public Health
DPH (10/00)

STATE OF WISCONSIN
HFS 157 ???

# Radioactive Materials Safety and Compliance Inspection Report

| 1. Licensee *Name and Address* | State of Wisconsin<br>Department of Health and Family Services<br>Radiation Protection Section<br>1 West Wilson Street<br>Madison, WI 53701-2659 |
|---|---|
| 2. License Number | 3. Inspection Date |

## Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Department of Health and Family Services (DHFS) Chapter HFS 157 'Radiation Protection' and the conditions of your license. The inspection consisted of selective examination of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. The violation(s) specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken.
_____ non-cited violation(s) were discussed involving the following requirement(s):_____

☐ 3. During this inspection certain of your activities, as described below and/or attached, were in violation of DHFS requirements and are being cited. This form is a NOTICE OF VIOLATION, which is required to be posted in accordance with *s. HFS 157.88 (4)*

## STATEMENT OF CORRECTIVE ACTIONS

**I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements (corrective steps already taken, corrective steps which will be taken, date of full compliance will be achieved) of *s. HFS 157.91*. I understand that no further written response to DHFS will be required, unless specifically requested.**

| SIGNATURE – Licensee | Printed Name | Date Signed |
|---|---|---|
| SIGNATURE – DHFS Inspector | Printed Name | Date Signed |

# Radioactive Materials Safety and Compliance Inspection Report Attachment

| 1. Licensee *Name and Address* | State of Wisconsin<br>Department of Health and Family Services<br>Radiation Protection Section<br>1 West Wilson Street<br>Madison, WI 53701-2659 |
|---|---|
| 2. License Number | 3. Inspection Date |

☐ *(Continued)*

## EXAMPLES OF VIOLATIONS THAT CAN BE CITED ON WISCONSIN FORM 591

1. Inventories not performed at the required frequency on one or two occasions that did not result in any consequences (e.g. lost material).

2. Licensee observed eating, drinking, etc. in laboratories where less than or equal tomegabequerel (microcurie) quantities of unsealed radioactive materials are stored, but not being used (a survey should be performed to confirm the absence of contamination).

3. Failure to calibrate survey instruments, alarm rate meters, or pocket dosimeters at the required frequency on one or two occasions.

4. Failure to use a dedicated check source before each use of a survey instrument, on one or two occasions.

5. Failure to perform routine surveys (e.g. radiation, contamination, airflow checks, or fume hood monitoring) at the required frequency on a few occasions.

6. Failures of the radiation safety committee to meet at the required frequency on one or two occasions.

7. Failure to have required attendees at all radiation safety committee meetings.

8. Rare failures to exchange personnel dosimetry at the required frequency, but with no loss of dosimetry data.

9. Failure to have properly prepared shipping papers.

10. Failure to include the emergency phone number, reportable quantity (RQ) designation or SI units on shipping papers.

11. Occasional failure to meet all transportation requirements of 49 CFR.

12. Users of radioactive materials are adequately trained, but not as stated in the license tie-down conditions.

13. On rare occasions, dose calibrator tests are not performed as required.

14. Isolated cases of missed or late leak tests.

15. Missed dose calibrator tests.

16. Failure to appropriately post areas where radioactive materials are stored or used.

*Note* This list is not all-inclusive. Most Severity Level IV & V violations may be cited on a WI Form 591 if they are not repetitive and are corrected within 30 days.

# Appendix A

**Wisconsin Department of Health and Family Services**
**Radiation Protection Section**
**Inspection Report**

# Portable Moisture/Density Gauges
# X-ray Fluorescence Measuring Devices

## Licensee and Inspector Information

| | |
|---|---|
| **License/Registration No.:** | **Inspection Date:** |
| **Licensee** (name and address): | |
| **Inspection Site Address** (authorized use): | |
| **Licensee Contact:** | **Contact Telephone No.:** |
| **Date of Last Inspection:** | **Type of Inspection(s):** |
| **Priority:** | |
| **Next Inspection Date:** ☐ Normal ☐ Reduced ☐ Extended | |
| **Justification(s) for change in Inspection Sequence** | |

**Summary of Findings and Actions** **[157.06(2)(c)]**

- ☐ No Violations Cited
- ☐ Violation(s) Issued
- ☐ Repeat Violations

**Lead Inspector:**
(Sign Name)_____ Date_____
(Print Name)_____

**Accompanying Inspector:**
(Sign Name)_____
(Print Name)_____ Date_____

**Reviewed By:**
(Sign Name)_____
(Print Name)_____ Date_____

**Notes:**

## Inspection Objectives

1. To determine if licensed activities are being conducted in a manner that will protect the health and safety of the workers and general public.

2. To determine if the licensed programs are being conducted in accordance with the State of Wisconsin Department of Health and Family Services Radiation Protection Standards of Chapter HFS 157.

## Inspection Preparation

1. Review licensee's documents

2. Review all license condition(s) and amendment(s) issued since the last inspection.

3. Check to see if the licensee has informed the Department of any major program changes.

4. Review Information Notices for recent information pertaining to portable gauges or XRFs.

5. Review Nuclear Material Events Database (NMED) files for regional and local notices of incidents and/or events.

6. Check previous inspection history for any cited Notice of Violation(s) (NOV), Responses, Recommendations and Safety Items, etc.

7. Select survey meter suitable for obtaining radiation level measurements (unless leaking source/contamination is suspected).

# Inspection Report /Checklist

## 1. Amendments and Program Changes: (Review from last License renewal) ch. HFS 157.13(13)

| a. Amendment # | b. Date: | c. Subject/Items. |
|---|---|---|
| | | |

Note:

## 2. Organization: ch. 157.13(2)(b)

a. **Briefly describe licensee organizational structure pertaining to licensed activities.**

b. **Organizational structure meets requirements as identified on license.** ☐ Yes ☐ No

c. **Radiation Safety Officer (RSO) identified on license.** [L/C] ☐ Yes ☐ No

(1) Performs duties required of RSO. [L/C] ☐ Yes ☐ No

(2) To whom does the RSO report?

d. **Identify and record all individuals in attendance at entrance meeting.** (attach additional sheets)

Individual 1:

Individual 2:

Individual 3:

Individual 4:

## 3. Scope of Licensee Program

a. **Permanent location and temporary jobsites of portable gauge use are identified on license.** ☐ Yes ☐ No

(1) Has the mailing address or place of use changed? ☐ Yes ☐ No ☐ N/A

(2) Has ownership changed? Was the department notified? ☐ Yes ☐ No ☐ N/A

(3) List the location(s) inspected.

b. **Authorized temporary jobsites.** ☐ Yes ☐ No ☐ N/A

(1) List location(s) of field inspection.

c. **List individuals interviewed at permanent and/or temporary jobsites during the inspection.**
** Indicates those individuals in attendance at exit meeting

Individual 1:

Individual 2:

Individual 3:

**d. Briefly describe the licensed material program. (who, what, when, how things are done)**
Note: Request a copy of the licensee's most recent inventory of radioactive material.

| Mfg. | Receipt | Disposal/ Transfer | Model # | Isotope | Activity (mCi) | Source # | Leak Test |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Note: Use attached supplementary gauge inventory sheet if needed.

**e. Does the licensee maintain a utilization log for each gauge? [157.45(6)]** ☐ Yes ☐ No

**Note:**

## 4. Management Oversight:

**a. Management supports ALARA.** **[157.21(2)]** ☐ Yes ☐ No

**b. Management supports RSO efforts.** ☐ Yes ☐ No

**c. Are the radiation protection annual audits being performed?** **[157.21(3)]** ☐ Yes ☐ No

(1) Audits are conducted by?

(2) Scope (areas of the program reviewed).

(3) Are audit records being maintained as required? **[157.31(a)(2)]** ☐ Yes ☐ No

(4) Did department Inspector review licensee audit records? ☐ Yes ☐ No

**d. Performance evaluation factors (P.E.F.).**

(1) Senior Management involvement with radiation safety program and RSO oversight. ☐ Yes ☐ No

(2) The RSO too busy with other assignments. ☐ Yes ☐ No

(3) Sufficient staffing for licensee program. ☐ Yes ☐ No

(4) Adequate audits are being implemented. ☐ Yes ☐ No

**Note:**

## 5. Inspection History

a. **Is this an initial application?** ☐ Current Rule [HSS 157] ☐ Yes ☐ No
☐ Agreement State Rule [HFS 157]

b. **Last inspection date.**

c. **List previous items of violations cited at last inspection.**

d. **Have previous violation(s) been properly corrected?** ☐ Yes ☐ No ☐ N/A
If no, list those violation(s) not corrected with an explanation.

e. **List previous items of recommendations**

## 6. Staff Training Program:

a. Training course for gauge users provided by manufacturer. ☐ Yes ☐ No

b. **Equivalent course approved by the Department. (Appendix D. of WISREGS)** ☐ Yes ☐ No ☐ N/A
**If no, who was the Trainer/Instructor?**

(1) Subjects/Topics covered:

(2) Did the course exam consist of 25-50 questions/closed book and a passing grade of 70% or above?
☐ Yes ☐ No

c. **All trained authorized users have been approved in writing by the RSO.** ☐ Yes ☐ No
**(attach list of authorized users) [L/C]**

(1) Documentation of training for authorized users is available for department review. ☐ Yes ☐ No

d. **During the department inspection, workers were interviewed and observed using the gauge.**
☐ Yes ☐ No

**If yes, briefly describe who was interviewed and what was observed.**

(1) Are individual(s) authorized to perform Non-Routine maintenance on gauges? ☐ Yes ☐ No ☐ N/A

If yes, list the individual(s) and review the documented training and procedures used

(2) Does the gauge user know what to do in case of an emergency? Are there written operating procedures?
☐ Yes ☐ No

(3) Where there any emergencies since last inspection? If so, was the Department notified? ☐ Yes ☐ No

(4) Do users have a copy of WI ***"Radiation Protection Standards"*** Chapter HFS 157 available to them.
☐ Yes ☐ No

## 7. Posting: ch. HFS 157.88 and 29(2)

a. **Radiation areas properly posted. (Required if >0.05 Sv (5 mR) /Hour @ 30 cm from container surface) [ 157.29 (3)(d)]** ☐ Yes ☐ No ☐ N/A

(1) "Caution Radioactive Material" signs posted where required. **[157.29 (4)(a)]** ☐ Yes ☐ No

b. **Department's "Notice to Employee" posted in an appropriate area? [157.88 (1)(a)(7)]** ☐ Yes ☐ No

c. **Department's rules and license are posted, or a posting indicating where these documents can be reviewed?[157.88 (1) (b)]** ☐ Yes ☐ No ☐ N/A

Note:

## 8. Labeling: ch. HFS 157.29 (4)

a. **All labels for gauges and XRF containers/devices are properly attached and legible. They must include symbols, isotope, activity, etc.** ☐ Yes ☐ No

## 9. Leak Test ch. HFS 157.24

a. **Leak test performed at 6 months intervals as required? [157.24 (1)(a)(2)]** ☐ Yes ☐ No

(1) Test kit model number: Kit Mfg:

(2) The Department inspector observed a user taking leak test samples? ☐ Yes ☐ No ☐ N/A

(3) Records of test for leakage are maintained for the department review for a period of 5 years for the date they were created. **[157.31 (4)]** ☐ Yes ☐ No

b. **Licensee performs own leak test. [157.24 (3)]** ☐ Yes ☐ No ☐ N/A

(1) Who is authorized to perform the leak tests?

(2) If (b) is yes, are procedures followed as described in Criteria of Appendix J of WISREG? ☐ Yes ☐ No

c. **Leak test results are available for the department to review.** ☐ Yes ☐ No

d. **Leak test results are reported in Becquerels or Microcuries. [157.31 (4)]** ☐ Yes ☐ No

e. **Report of leaking source made to the Department since last inspection? [157.37 (7)]** ☐ Yes ☐ No

## 10. Facilities, Materials and Equipment: ch. 157.28 (1)

a. **Describe use and storage area(s).**

(1) Same as described in license. **[L/C]** ☐ Yes ☐ No

(2) Radioactive material, not in storage, is secured against unauthorized removal from an unrestricted area. [157.28 (1)(b)] ☐ Yes ☐ No

(3) Adequate controls in place to prevent unauthorized access to radioactive materials in unrestricted areas. [157.28 (1)(a)] ☐ Yes ☐ No

**b. Survey instruments are required.** [157.25] [L/C] ☐ Yes ☐ No ☐ N/A

(1) Does licensee have a survey meter available? ☐ Yes ☐ No

(2) Surveys performed to ensure the public dose will not exceed [100 mR/year or 2mR/hr in any one hour]? ☐ Yes ☐ No ☐ N/A

(3) Survey records kept for three years. ☐ Yes ☐ No ☐ N/A

**c. Calibration of instrument(s) at intervals not exceeding 12 months.** 157.25 (1)(b)] ☐ Yes ☐ No

(1) Calibration reports kept for three years? ☐ Yes ☐ No

**d. A survey instrument is accessible to licensee if needed?** [L/C] ☐ Yes ☐ No

## 11. Radiological Protection Procedures:

**a. Gauges and devices are used in accordance with their SSD certification?** ☐ Yes ☐ No

**b. Workers have an adequate understanding of the procedures and rules for the safe use of radioactive materials?** ☐ Yes ☐ No

(1) The user understands the Operating and Emergency Procedures? ☐ Yes ☐ No

**c. Any changes in O&E procedures since last inspection?** ☐ Yes ☐ No ☐ N/A

(1) Where changes authorized by the Department? If yes, describe the changes. ☐ Yes ☐ No ☐ N/A

## 12. Receipt and Transfer of Radioactive Material: ch. 157.29(6)

**a. Describe how packages are received. Who receives them?**

**b. The licensee has package receipt procedures in place?** ☐ Yes ☐ No

**c. Transfer of radioactive material as authorized?** [157.13 (15)] ☐ Yes ☐ No ☐ N/A

**d. Records of receipts, transfers and disposals of licensee's radioactive material are maintained for three years for department's review?** [157.06] ☐ Yes ☐ No ☐ N/A

**Note:**

## 13. Independent Survey Measurements by the Department Inspector: ch. 157.06 (3)

**a. Inspector performed independent confirmatory surveys (compare licensee meter readings to inspector's meter readings)?** ☐ Yes ☐ No ☐ N/A

**b. Survey instrument used:**

(1) Mfg./Make:

(2) Model #:

(3) Serial #:

(4) Last calibration date:

Note:

**c. Licensee survey instrument(s): (if one available)**

(1) Mfg./Make:

(2) Model #:

(3) Serial #:

(4) Last calibration date:

Note:

**d. Describe inspector instrument readings as compared to licensee instrument readings.**

**e. Independent meter measurements:**

(1) Highest radiation level in unrestricted area? (mR)/hr

(2) Highest radiation level at 30cm from storage container? (mR)/hr

(3) Reading at external surface of transportation container? (mR)/hr

**f. Radiation level in all unrestricted areas are less than: 0.02 mSv/hr (2 mR/hr) in any one hour and less than 100 mR/yr.** ☐ Yes ☐ No

## 14. Personnel Monitoring: ch. 157.25 (2)

**a. Dosimetry required?** **[157.25 (2)(a)(6)] [L/C]** ☐ Yes ☐ No

☐ Moisture Density Gauge User ☐ XRF User

**b. Dosimeter provided to workers?** ☐ Yes ☐ No ☐ N/A

☐ Film ☐ TLD ☐ Other

(1) Frequency of dosimeter reports? ☐ Monthly ☐ Quarterly

(2) Film / TLD Supplier?

(3) Supplier NVLAP certified? **[157.25 (1)(c)(2)]** ☐ Yes ☐ No

**c. Monitoring reports reviewed by licensee?** **[L/C]** ☐ Monthly ☐ Quarterly ☐ Annually

d. **Personnel monitoring records recorded on department form or equivalent method?** ☐ Yes ☐ No ☐ N/A

(1) Monitoring results are reported in Sv or Rem? **[157.13 (1)]** ☐ Yes ☐ No

e. **Review of personnel monitoring records, from** to

(1) Max. DDE mR ☐ Month ☐ Quarter ☐ Year

(2) Max. SDE mR ☐ Month ☐ Quarter ☐ Year

f. **Did any workers occupational dose exceed regulatory limits?** **[157.22 (1)(a)]** ☐ Yes ☐ No

g. **Pocket dosimeters used?** ☐ Yes ☐ No ☐ N/A

(1) Mfg. of dosimeter:

(2) Model / Serial Number:

(3) Dose Range mR Rads

h. **Are records of personnel occupational dose being retained? (Must keep until department or licensee terminates license)** **[157.31 (7)(6)]** ☐ Yes ☐ No

## 15. Instructions to Workers: ch. 157.88 (2)

a. **Training is provided to all individuals / workers who are likely to receive an occupational radiation dose [>100mR/yr]?** ☐ Yes ☐ No ☐ N/A

(1) Workers are kept informed of their occupational exposures? **[157.88 (2)(a)]** ☐ Yes ☐ No

(2) Workers are provided refresher training as needed? ☐ Yes ☐ No

b. **Required monitoring records are maintained for three years?** **[157.88 (3)(b)]** ☐ Yes ☐ No

## 16. Notifications and Reports: ch. 157.32 (2)

a. **Did the licensee provide all gauge users a written report of their annual radiation exposure?** **[157.88 (3)(b)]** ☐ Yes ☐ No

(1) Are the occupational radiation exposure reports being maintained? ☐ Yes ☐ No

b. **At termination of employment, are workers exposure records available upon request?** **[157.88 (3)(c)]** ☐ Yes ☐ No

c. **Has any theft or loss of licensed material occurred since the last inspection?** **[157.32]** ☐ Yes ☐ No

d. **Has there been a reportable incident since the last inspection?** **[157.32]** ☐ Yes ☐ No

(1) If yes, describe the root cause and corrective actions taken for each incident.

| | | | |
|---|---|---|---|
| e. **Has any occupational overexposure or excessive levels of radiation been reported to the department?** | **[157.32 (3)]** | ☐ Yes | ☐ No |
| **17. Transportation of Radioactive Materials:** | | **ch. 157.92 and 49 CFR 171-178** | |
| a. **Licensee makes shipments of radioactive material?** | | ☐ Yes | ☐ No |
| (1) Security and all applicable regulations followed? | **[157.92 (3)]** | ☐ Yes | ☐ No |
| b. **Shipments are made through common carriers?** | | ☐ Yes | ☐ No |
| c. **Shipments are transported in licensee private vehicle(s)?** | | ☐ Yes | ☐ No |
| d. **Are both methods b. and c. are used?** | | ☐ Yes | ☐ No |
| e. **Were shipments made since the last inspection?** | | ☐ Yes | ☐ No |

**The following items are to be completed if shipments were made since last inspection**
**Note:** See Section 18 if inspecting a licensee that is authorized to use XRFs

| | | | | | |
|---|---|---|---|---|---|
| a. **Devices packaged and shipped according to regulatory procedures?** | | ☐ Yes | ☐ No | | |
| (1) Package type used for shipping? | | | | | |
| b. **Package / container meets design requirements?** | **[49 CFR 173.410]** | ☐ Yes | ☐ No | | |
| (1) DOT 7-A performance test records on file? | **[49 CFR 173.415 (a)]** | ☐ Yes | ☐ No | ☐ N/A | |
| (2) Package labeled properly (yellow II), TI, nuclide, activity, etc.)? | | ☐ Yes | ☐ No | ☐ N/A | |
| (3) Activity per instrument does not exceed A-1 limit. | **[49 CFR 173.424 (b)]** | ☐ Yes | ☐ No | | |
| (4) Activity per package does not exceed A-1 limit. | **[49 CRF 173.424]** | ☐ Yes | ☐ No | | |
| (5) Radiation levels at 10cm from surface of the device read less that 10mR/hr? | **[49 CFR 173.424 (d)]** | ☐ Yes | ☐ No | | |
| (6) Radiation levels at the external surface of the package read less than 2 mR/hr? | | ☐ Yes | ☐ No | ☐ N/A | |
| (7) All proper shipping requirements are met (shipper's name, description of shipment, hazard class, UN number, nuclide, RQ, activity category label, TI, etc.)? | **[49 CFR 172.200-204]** | ☐ Yes | ☐ No | ☐ N/A | |
| (8) Emergency procedures and response telephone number(s) available? | **[49 CFR 172.201 (d)]** | ☐ Yes | ☐ No | ☐ N/A | |
| (9) Shipper papers readily accessible during transportation? | **[49 CFR 177.81 (e)]** | ☐ Yes | ☐ No | ☐ N/A | |
| (10) Gauge blocked, braced and secured? | **[ 49 CFR 177.82 (d)]** | ☐ Yes | ☐ No | ☐ N/A | |
| (11) Special Form Sources Certificate, Certificate of Compliance and performance test records on file? | **[49 CFR 173.476 (a)]** | ☐ Yes | ☐ No | ☐ N/A | |
| (12) Vehicle placarded as required (yellow III, if TI>1.0)? | **[49 CFR 172.504 (a)]** | ☐ Yes | ☐ No | ☐ N/A | |
| (13) Proper Over-packs used and labeled? | **[49 CFR 173.25]** | ☐ Yes | ☐ No | ☐ N/A | |
| (14) Hazmat training? | **[49 CFR 172.704]** | ☐ Yes | ☐ No | ☐ N/A | |

*The following section pertains to XRFs ONLY*

## 18. Transportation Requirements for XRFs (Instruments & Articles):

| | | | |
|---|---|---|---|
| a. Devices transported as "excepted" packages for instruments and articles? | [49 CFR 173.424] | ☐ Yes | ☐ No |
| (1) Package meets general design requirements? | [49 CFR 173.410] | ☐ Yes | ☐ No |
| (2) Activity per instrument does not exceed 10E-2, A-1 limit? | [49 CFR 143.424(b)] | ☐ Yes | ☐ No |
| (3) Activity per package does not exceed A-1 limit? | [49 CFR 173.424(c)] | ☐ Yes | ☐ No |
| b. Highest radiation level at 10 cm from unpacked instrument is less than 10mR/hr? | | ☐ Yes | ☐ No |
| c. Highest radiation level on the external surface of package is less than 0.5mR/hr? | | ☐ Yes | ☐ No |
| d. The excepted package, when prepared for shipping, is accomplished by a notification certifying the package conditions and limitations? | [49 CFR 173.422] | ☐ Yes | ☐ No |

*For Labeling, See Section 8 of this report* — ch. 49 CFR 172.403 (b) & 172.403 (a)

| 19. License Conditions / Tie-downs: | | |
|---|---|---|
| a. All license conditions reviewed? | ☐ Yes | ☐ No |
| b. Licensee activities were conducted in accordance with license conditions? | ☐ Yes | ☐ No |
| **20. Bulletins and Information Notices:** | | |
| a. The licensee is receiving the department information notices and bulletins? | ☐ Yes | ☐ No |
| (1) Licensee has taken appropriate action in response to the bulletins and notices? | ☐ Yes | ☐ No |

| 21. Exit Meeting at Conclusion of Inspection: |
|---|
| a. Identify and list the individuals in attendance. Date Conducted: |
| |
| |
| |
| |
| |
| |
| Note: |
| b. List those issues discussed at the exit meeting. |
| |
| 22. Summary of Violations and Recommendations: |
| |

# Wisconsin Department of Health and Family Services
# Radiation Protection Section
# Inspection Report

## FIXED GAUGES

**Licensee and Inspector Information:**

| **License/Registration No.:** | **Inspection Date:** |
|---|---|
| **Licensee** (name and address): | |
| **Inspection Site Address** (authorized use or storage): | |
| **Licensee Contact:** | **Contact Telephone No.:** |
| **Date of Last Inspection:** | **Type of Inspection(s):** ☐ Announced ☐ Unannounced ☐ Initial ☐ Routine |

**Priority:**

**Next Inspection Date:**

☐ Normal ☐ Reduced ☐ Extended

**Justification(s) for change in Inspection Sequence:**

**Summary of Findings and Actions:** [157.06(2)(c)]

☐ Violation(s) Issued ☐ Repeat Violations ☐ No Violations Cited

**Lead Inspector:**

(Sign Name)_____ Date_____ _____

(Print Name)_____

**Inspector:**

(Sign Name)_____

(Print Name)_____ Date_____ _____

**Reviewed By:**

(Sign Name)_____ Date_____ _____

(Print Name)_____

**Notes:**

**Inspection Objectives:**

1. To determine if licensed activities are being conducted in a manner that will protect the health and safety of the workers and general public.

2. To determine if the licensed programs of fixed gauges are being conducted in accordance with Wisconsin Department of Health and Family Services, Radiation Protection Standards of Chapter HFS 157.

**Inspection Preparation:**

1. Review licensee's documents on file.
2. Review all license condition(s) and amendment(s) issued since the last inspection.
3. Check to see if the licensee has informed the Department of any major program changes.
4. Review Nuclear Material Events Database (NMED) files for regional and local notices of incidents and / or events.
5. Check previous inspection history for any cited Notice of Violation(s) (NOV), Responses, Recommendations and Safety Items, etc.
6. Select survey meter suitable for obtaining radiation level measurements (unless leaking source/contamination is suspected).

| Inspection Report /Checklist | | ch. HFS 157.89 |
|---|---|---|
| **1. Amendments and Program Changes:** (Review from last license renewal) | | **ch. HFS 157.13(13)** |
| **a. Amendment #** | **b. Date:** | **c. Subject/Items:** |
| | | |
| **Note:** | | |
| **2. Organization:** | | **ch. HFS 157.13(2)(b)** |
| **a. Briefly describe licensee organizational structure as it pertains to licensed activities.** | | |
| **b. Organizational structure meets requirements as identified on license.** ☐ Yes ☐ No | | |
| **c. Radiation Safety Officer (RSO) identified on license.** [L/C] ☐ Yes ☐ No | | |
| (1) Performs duties as required of RSO. (Appendix C WisRegs) [L/C] ☐ Yes ☐ No | | |
| (2) To whom does the RSO report? | | |
| (3) Has there been a change in the RSO? Was the license amended? ☐ Yes ☐ No ☐ N/A | | |
| **d. Has there been a change in the licensee contact person for the Department?** ☐ Yes ☐ No | | |
| **e. Identify and record all individuals in attendance at entrance meeting.** (attach additional sheets) | | |
| Individual 1: | | |
| Individual 2: | | |
| Individual 3: | | |
| Individual 4: | | |

**3. Scope of Licensee Program:**

**a. Locations of fixed gauges identified on license.** ☐ Yes ☐ No

(1) Has the address(s) or location of fixed gauges changed? ☐ Yes ☐ No ☐ N/A

(2) Has ownership changed? Was the department notified? ☐ Yes ☐ No ☐ N/A

(3) List location(s) of radioactive sources/ devices and identify location of inspection.

**b. Personnel interviewed at licensee address during the inspection.** (*attach additional sheets*)

** Indicates those individuals in attendance at exit meeting

Individual 1:

Individual 2:

Individual 3:

Individual 4:

**Note:**

**c. Briefly describe the license material program:** (who, what, when, how things are done, etc)

**Note:** the inspector should request a copy of licensee's most recent inventory of sources.

(1) Fixed gauges are secured and used, consistent with manufacturer recommendations or conditions of authorized use listed on the license? **[L/C]** ☐ Yes ☐ No

(2) Manufacturer's / distributor's manual for operation and maintenance for each type of fixed gauges in use are available. ☐ Yes ☐ No

**Note:** check SSD registration certificate.

**Use the attached gauge inventory sheet for additional entries.**

| Manufacturer | Receipt | Disposal | Transfer | Model # | Isotope | Activity(mCi) | Source # | Leak Test Date: |
|---|---|---|---|---|---|---|---|---|

**Note:**

**4. Management Oversight:**

**a. Management supports ALARA.** **[157.21(2)]** ☐ Yes ☐ No

**b. Management supports RSO efforts.** ☐ Yes ☐ No

**c. Radiation protection annual audits are being performed? [157.21(3)]** ☐ Yes ☐ No

(1) Audits conducted by?

(2) Scope of audit (areas of the program licensee reviewed)

(3) Audits and review records of the licensee program are being maintained. **[157.31(a)(2)]**
**Note**: These records must be kept for three years after they are made. ☐ Yes ☐ No

(4) Audits conducted at intervals not exceeding 12 months. **[157.21]** ☐ Yes ☐ No

(5) Deficiencies found in the program during the licensee last two audits? ☐ Yes ☐ No
If yes, have the deficiencies been corrected?

(6) Records reviewed by department Inspector. ☐ Yes ☐ No

**e. Performance evaluation factors ( P.E.F.).**

(1) Senior management is involved with the radiation safety program oversight. ☐ Yes ☐ No

(2) RSO too busy with other duties. ☐ Yes ☐ No

(3) Sufficient staffing to support licensee program. ☐ Yes ☐ No

(4) Adequate audits of the licensee program. ☐ Yes ☐ No

## 5. Inspection History of Licensee's Program:

**a. Is this an initial inspection?** ☐ State (**HSS 157**) ☐ Yes ☐ No ☐ Agreement State (**HFS 157**) ☐ Yes ☐ No

**b. Last inspection date at this location.**

**c. List previous items of violations:**

**d. Have previous violation(s) been properly corrected?** ☐ Yes ☐ No
If no, list those violations not corrected with an explanation.

**e. List previous items of recommendations:**

**f. Did licensee address previous recommendation(s)** ☐ Yes ☐ No ☐ N/A
If no, explain.

## 6. Staff Training Program:

**a. Did each authorized user receive training or instructions from the manufacturer at the time that the gauge(s) were installed?** ☐ Yes ☐ No

**b. An equivalent training course approved by the department was given. (Appendix G of WisRegs)** ☐ Yes ☐ No

(1) Who was the Trainer/Instructor?

(2) List subjects/topics covered:

(3) List the individuals considered trained and approved by the RSO as authorized users. **[L/C]**

**Note:** Inspector should check training records for each authorized user.

**c. Personnel working in the vicinity of a fixed gauge have completed a 1 to 2 hour safety orientation course?** ☐ Yes ☐ No

(1) List workers who took the orientation course and were approved in writing by the RSO. **[L/C]**

**d. All training records are available for the department review.** ☐ Yes ☐ No

**e. During the department inspection, did the inspector observe the user performing routine maintenance on the gauges?** ☐ Yes ☐ No

If yes, briefly describe who was interviewed and what was observed.

(1) Inspector observed gauges being used. ☐ Yes ☐ No

(2) Personnel authorized to perform **Non-Routine** maintenance on gauges? ☐ Yes ☐ No

If yes, list individual(s) and review documented training and procedures use.

(3) The gauge users know what to do in case of an emergency? ☐ Yes ☐ No

(4) Are there written operating and emergency procedures? ☐ Yes ☐ No

(5) Have there been any emergencies since last inspection? ☐ Yes ☐ No ☐ N/A
If yes, was the department notified?

(6) Workers have a copy of WI " Radiation Protection Standards" ch. HFS 157 available to them.
☐ Yes ☐ No

## 7. Notification and Reports: ch. HFS 157.32(2)

**a. Did the licensee provide all fixed gauge users, with badges, a written annual report of their radiation exposure? [157.88(3)(b)]** ☐ Yes ☐ No ☐ N/A

(1) The occupational radiation exposure reports are maintained? ☐ Yes ☐ No

(2) At termination of employment, are worker's exposure records available to he/she upon request?
**[157.88(3)(c)]** ☐ Yes ☐ No

**b. Has any theft or loss of licensed material occurred since the last inspection? [157.32(1)]**
☐ Yes ☐ No

**c. Has there been any reportable incident since last inspection? [157.32(2)] & [.13(10)]**
☐ Yes ☐ No

If yes, describe the root cause and corrective actions taken.

**d. Has any occupational overexposure or excessive levels of radiation been reported to the department? [157.32(3)]** ☐ Yes ☐ No

**e. The RSO and all authorized users are aware of the department's emergency telephone number.**
**Note:** Dept 24-hour emergency # (608) 258 0099 ☐ Yes ☐ No

**8. Posting:** **ch. HFS 157.88 and .29(2)**

a. **Fixed gauge locations are properly posted.** **[157.29(2)(d)]** ☐ Yes ☐ No
Note: Required if reading is >5mR/hr@ 30 cm from gauge's surface. **[157.29(3)(a)]**

b. **"Caution- Radioactive Material" or danger signs posted where required. [157.29(2)(e)]** ☐ Yes ☐ No ☐ N/A

c. **Is there a warning signal at or near the gauge to indicate that the shutter is open?** **L /C** ☐ Yes ☐ No ☐ N/A

d. **The department's " Notice to Employe" posted in an appropriate area. [157.88(1)(a)7]** ☐ Yes ☐ No

e. **The department's Rules and license are posted, or a notice posted where those documents can be viewed.** **[157.88(1)(b)]** ☐ Yes ☐ No

**9. Labeling:** **ch. HFS 157.29(4)**

a. **Fixed gauge device labels are attached and legible with symbols, isotope, activity "Caution- Radioactive Material".** **[157.29(4)(a)]** ☐ Yes ☐ No

b. **Authorized users have available, a copy of the licensee's "Lock Out" procedures?** ☐ Yes ☐ No

(1) "Lock Out" warning signs are posted at all entryways where it is possible to be exposed. ☐ Yes ☐ No ☐ N/A

**10. Leak Test:** **ch. HFS 157.24**

a. **Leak test performed on each sealed source at 6 months intervals as.** **[157.24(1)(a)2]** ☐ Yes ☐ No

(1) Kit Mfg.: Test kit model number:

(2) The department inspector observed or requested a demonstration of the user taking a leak test sample. ☐ Yes ☐ No ☐ N/A

(3) Records for leakage test are maintained for the department review for a period of 5 years from the date they were made. **[157.31(4)]** ☐ Yes ☐ No

**b. Licensee performs own leak test.** **[157.24(3)]** ☐ Yes ☐ No ☐ N/A

(1) If (b) is yes, are procedures followed as described in Criteria of Appendix J of WisRegs? ☐ Yes ☐ No

**c. Leak test results are available for the department to review.** ☐ Yes ☐ No

**d. Leak test results are reported in Becquerels or Microcuries. [157.31(4)]** ☐ Yes ☐ No

**e. Any leaking sources since last inspection?** **[157.37(7)]** ☐ Yes ☐ No

## 11. Facilities, Materials and Equipment: ch. HFS 157.28(1)

**a. Use locations and storage area(s) described in license** **[L/C]** ☐ Yes ☐ No

(1) Fixed Gauges, not in storage, is secured against unauthorized removal from an unrestricted area. **[157.28(1)(b)]** ☐ Yes ☐ No

(2) Adequate controls in place to prevent unauthorized access to gauge in restricted areas. **[157.28(1)(a)]** ☐ Yes ☐ No

(3) The licensee owns the property where the gauge is use and stored. [L/C] ☐ Yes ☐ No
If no, does the department have a letter on file from property owner?

**b. Survey instruments are required.** [L/C] ☐ Yes ☐ No ☐ N/A
**Note:** For non-routine operations, a survey instrument is required [157.25(1)]

(1) Does licensee have a survey meter available them. [L/C] ☐ Yes ☐ No

(2) Surveys are performed to ensure the public dose will not exceed 100mR/year. ☐ Yes ☐ No ☐ N/A

(3) Survey records kept for three years from date they are made. ☐ Yes ☐ No ☐ N/A

**c. Instrument Calibrations are done at intervals, not exceeding 12 months. [157.25(1)(b)** ☐ Yes ☐ No

(1) Calibration reports kept for three years from the date they are made. ☐ Yes ☐ No ☐ N/A

## 12. Radiological Protection Procedures:

**a. Fixed gauges are used in accordance with their SSD certification.** [157.13(2)] ☐ Yes ☐ No

(1) If a portion or all of a person body, can be access between the primary beam and the detector, the licensee must develop "lock out" procedures. Is there such a gauge at this facility? ☐ Yes ☐ No

**b. Operating and Emergency procedures are posted for each type of fixed gauge.** ☐ Yes ☐ No

**c. Workers have an adequate understanding of the procedures and rules for the safe use of radioactive materials and working in the vicinity of the fixed gauges.** ☐ Yes ☐ No

(1) The user understands the Operating and Emergency Procedures. [157.32] ☐ Yes ☐ No

(2) Were changes made to the O/E procedures since last inspection? ☐ Yes ☐ No ☐ N/A
If yes, describe the changes.

**13. Receipt and Transfer of Radioactive Material: ch. HFS 157.29(6)**

**a. Describe how fixed gauges are received. Who install them?**

**b. The licensee has package receipt procedures in place.** ☐ Yes ☐ No ☐ N/A

**c. Transfer of radioactive material as authorized. [157.13(15)]** ☐ Yes ☐ No ☐ N/A

**d. Records of receipts, transfers and disposals of licensee's radioactive material are maintained for three years for the department's review. [157.06]** ☐ Yes ☐ No

**14. Independent Survey Measurements by the department inspector: ch. HFS 157.06(3)**

**a. Inspector performed independent surveys.** ☐ Yes ☐ No

**b. Inspector survey instrument used:**

(1) Mfg. / Make:

(2) Model #:

(3) Serial #:

(4) Last calibration date:

**c. Licensee survey instrument(s): (if ones available)** ☐ N/A

(1) Mfg. / Make:

(2) Model #:

(3) Serial #:

(4) Last calibration date:

**d. Describe inspector instrument readings as compared to licensee instrument readings.**

**e. Independent measurements: (Confirmatory)**

(1) Highest radiation level in an unrestricted area. (mR)/hr

(2) Highest radiation levels at 30 cm from storage cabinet. (mR)/hr

(3) Highest radiation levels at 10 cm from device surface. (mR)/hr

(4) Reading at external surface of transportation container. (mR)/hr

**f. External radiation level, in all unrestricted areas, measured less than 2mR/hour and 100mR/year.** ☐ Yes ☐ No

**15. Personnel Monitoring:** **ch. HFS 157.25(2**

a. Dosimetry required. [L/C] **[157.25(2)(a) 6].** ☐ Yes ☐ No ☐ N/A

**b. Dosimeters provided to workers.** ☐ Yes ☐ No

**Note:** individuals who are likely to receive > 10% of their dose limits

(1) Type. ☐ Film ☐ TLD ☐ Other

(2) Frequency of dosimeter reports. ☐ Monthly ☐ Quarterly ☐ Other

(3) Dosimeter supplier:

(4) Supplier, NVLAP certified **[157.25(1)(c) 2].** ☐ Yes ☐ No

c. **Dosimeter reports reviewed by licensee.** **[L/C]** ☐ Monthly ☐ Quarterly ☐ Annually

d. **Personnel occupational dose records are maintained.** ☐ Yes ☐ No

(1) Occupational dose results are reported in Sv or Rem. **[157.31(1)]** ☐ Yes ☐ No

e. **Review of personnel monitoring records, from to**

(1) Max. DDE _____ ( mR) ☐ Monthly ☐ Quarterly ☐ Annually

(2) Max. SDE _____ ( mR) ☐ Monthly ☐ Quarterly ☐ Annually

f. **Did any workers occupational dose exceed the regulatory limits?** ☐ Yes ☐ No
**[157.2(1)(a)]**

g. **Records of personnel occupational dose history retained.[157.31(7) 6]** ☐ Yes ☐ No
**Note:** These records must be kept until license is terminated.

h. **Is public access to gauges, controlled in a manner that keeps the doses below 2mR/hour and 100mR/year?** **[157.23(1)]** ☐ Yes ☐ No

**16. Instructions to workers:** **ch. HFS 157.88(2)**

a. **Training is provided to all individuals / workers who are likely to receive an occupational radiation dose [>1mSv(100mR)/year] [When Badge]** **[157.88(2)(a)]** ☐ Yes ☐ No

(1) Monitored personnel are kept informed of their occupational exposures. ☐ Yes ☐ No

(2) Workers are provided refresher training as needed. **[157.88(2)]** ☐ Yes ☐ No

| | | | |
|---|---|---|---|
| **b. Monitoring records maintained for three years.** | **[157.88(3)(b)]** | ☐ Yes | ☐ No |

| **17. Transportation of Radioactive Material:** | **ch. HFS 157.29 and 49 CFR 171 -17** | | |
|---|---|---|---|
| **a. Licensee makes shipments of radioactive material.** | **[157.92(1)]** | ☐ Yes | ☐ No |
| (1) Security and all applicable regulations followed. | **[157.92(3)]** | ☐ Yes | ☐ No |
| **b. Shipments are made to common carriers.** | **[157.92(2)}** | ☐ Yes | ☐ No |
| **c. Shipments are transported in licensee private vehicle(s).** | **[157.92(3)]** | ☐ Yes | ☐ No |
| **d. No shipments made since last inspection.** | | ☐ Yes | ☐ No |

**ote: To be completed if shipments were made since last inspection. (e. through g.)**

| | | | |
|---|---|---|---|
| **e. Devices packaged and shipped according to regulatory procedures.** | **[157.94]** | ☐ Yes | ☐ No |
| **f. Package type used for shipping.** | **[157.94(1)(a)]** | | |
| **g. Package / container meets design requirements.** | **[49cfr173.410]** | ☐ Yes | ☐ No |
| (1) DOT 7A or other authorized packages used for shipping. | **[49cfr173.415(a)]** | ☐ Yes | ☐ No |
| (2) Package has two labels. (Yellow II with TI, Nuclide, Activity, and Hazard Class.) | | ☐ Yes | ☐ No |
| (3) Activity per gauge does not exceed A-1 limit. | **[49cfr173.424(b)]** | ☐ Yes | ☐ No |

(4) Activity per package does not exceed A-1 limit. **[49cfr173.424]** ☐ Yes ☐ No

(5) Radiation levels at 10cm from surface of the device, read less than 10mR/hr. **[49cfr173.424(d)]** ☐ Yes ☐ No

(6) Radiation levels at the external surface of the package read less than 2mR/hr. **[49cfr173.424(e)]** ☐ Yes ☐ No

(7) All proper shipping requirements are met. **[49cfr172.200-204]** ☐ Yes ☐ No

**Note:** shipper's name, description of shipment, hazard class, UN number, nuclide, total quantity, package type, RQ, physical/chemical form, activity, category label, TI, certification and signature(s), emergency phone numbers).

(8) Emergency procedures and response telephone number(s) available. **[49cfr172.201(d)]** ☐ Yes ☐ No

(9) Shipping papers prepared and used. ☐ Yes ☐ No

(10)Shipping papers are readily accessible to the driver during transportation. **[49cfr17177.842(d)]** ☐ Yes ☐ No

(11)Special form sources documentation on file. ☐ Yes ☐ No

(12)Vehicle placarded as required (yellow III, if TI> 1.0). **Note:** Only required with yellow lll labels. **[49cfr172.504(a)]** ☐ Yes ☐ No ☐ N/A

(13)Proper Over-packs used and labeled. **[49cfr173.25]** ☐ Yes ☐ No ☐ N/A

(14)Hazmat training. **[49cfr172.704]** ☐ Yes ☐ No ☐ N/A

**18. License Conditions / Tie-downs:**

**a. All license conditions reviewed by department Inspector.** ☐ Yes ☐ No

b. Licensee activities were conducted in accordance with license conditions. ☐ Yes ☐ No

**19. Information Notices:**

a. Licensee is receiving the department information notices and bulletins. ☐ Yes ☐ No

b. Licensee has taken appropriate action in response to the bulletins and notices. ☐ Yes ☐ No

**20. Exit Meeting at Conclusion of Inspection:**

a. Identify and list the individuals in attendance.

b. List those issues discussed at exit meeting.

**21. Summary of Violations and Recommendations:**

# Wisconsin Department of Health and Family Services
# Radiation Protection Section
# Inspection Report

## COMMERCIAL NUCLEAR PHARMACY

**Licensee and Inspector Information:**

| | |
|---|---|
| **License/Registration No.:** | **Inspection Date:** |
| **Licensee** (name and address): | |
| **Inspection Site Address** (authorized use or storage): | |
| **Licensee Contact:** | **Contact Telephone No.:** |
| **Date of Last Inspection:** | **Type of Inspection(s):** ☐ Announced ☐ Unannounced ☐ Initial ☐ Routine |

**Priority:**

**Next Inspection Date:**

☐ Normal ☐ Reduced ☐ Extended

**Justification(s) for change in Inspection Sequence:**

**Summary of Findings and Actions:** [157.06(2)(c)]

☐ Violation(s) Issued ☐ Repeat Violations ☐ No Violations Cited

**Lead Inspector:**

(Sign Name)_____ Date_____ _____

(Print Name)_____

**Inspector:**

(Sign Name)_____

(Print Name)_____ Date_____ _____

**Reviewed By:**

(Sign Name)_____ Date_____ _____

(Print Name)_____

**Notes:**

## Inspection Objectives:

1. To determine if licensed activities of a Nuclear Pharmacy are being conducted in a manner that will protect the health and safety of the users and general public.

2. To determine if the licensed programs of a Nuclear Pharmacy are being conducted in accordance with Wisconsin Administrative Code Chapter HFS 157 and license conditions.

## Inspection Preparation:

1. Review licensee's documents on file.
2. Review all license condition(s) and amendment(s) issued since the last inspection.
3. Check to see if the licensee has informed the Department of any major program changes.
4. Review Nuclear Material Events Database (NMED) files for regional and local notices of incidents and / or events.
5. Check previous inspection history for any cited Notice of Violation(s) (NOV), Responses, recommendations and Safety Items, etc.
6. Who is functioning as the licensee's Radiation Safety Officer (RSO)?
7. Who is functioning as the licensee's Authorized Nuclear Pharmacist (ANP)?
8. Who are the Authorized User(s) (AU)?
9. Nuclear pharmacy inspections are normally done early in the morning to catch the first production of radiopharmaceuticals.

| nspection Report /Checklist | ch. HFS 157.89(1); & .06(2) |
|---|---|

**1. Amendments and Program Changes (Review from last license renewal)** — ch. HFS 157.13(13)

| a. Amendment # | b. Date: | c. Subject/Items: |
|---|---|---|
| | | |

**Note:**

**2. Organization:** — ch. HFS 157.13(2)(b)
Note: request organizational chart.

**a. Briefly describe licensee organizational structure as it pertains to licensed activities.**

**b. Organizational structure meets requirements as identified on license.** ☐ Yes ☐ No

**c. Radiation Safety Officer (RSO) identified on license. [L/C] [157.13(2)]** ☐ Yes ☐ No

(1) Performs duties as required of RSO. (Appendix H WisRegs) **[L/C]** ☐ Yes ☐ No

(2) To whom does the RSO report?

(3) The RSO has sufficient access to licensee's senior management? ☐ Yes ☐ No

(4) Has there been a change in the RSO? ☐ Yes ☐ No ☐ N/A

(5) Was the license amended? ☐ Yes ☐ No ☐ N/A

(6) Does the new RSO meet department's training requirements? ☐ Yes ☐ No ☐ N/A

**d. Has there been a change in the licensee contact person for the Department?** ☐ Yes ☐ No

Note: Confirm through discussions with management and licensee personnel whether changes have occurred in licensee ownership, changes in the RSO authority or duties that may impact his/her ability to safely conduct the licensee's radiation protection program.

**e. Identify and record all individuals in attendance at entrance meeting.** (attach additional sheets)

Individual 1:

Individual 2:

Individual 3:

Individual 4:

Individual 5:

**3. Scope of Licensee Program:**

**a. Location(s)where licensed materials are being used, possessed and stored by the licensee is described on the license.** **[157.13(10)(c)]** ☐ Yes ☐ No

(1) Mailing address or location of possessed licensed materials has changed? **[157.13(9)(b)]** ☐ Yes ☐ No ☐ N/A

(2) Has ownership changed? Was the department notified? **[157.13(9)(b)] & .10]** ☐ Yes ☐ No ☐ N/A

(3) List location(s) of licensed materials and identify the location of this inspection.

**b. Authorized Nuclear Pharmacist (ANP) is named on the license, with appropriate training documentation.** **[157.13(4) &157.03]** ☐ Yes ☐ No

(1) A new Authorized Nuclear Pharmacist (ANP) since the last inspection? ☐ Yes ☐ No ☐ N/A

(2) If so, does the new ANP meet the department's training requirements? **[157.61(9) and L/C]** ☐ Yes ☐ No ☐ N/A

(3) The department was notified within 30 days with an amendment to the license? **[157.13(5)(c)]** ☐ Yes ☐ No

Note: Request a list of names of the RSO, ANP and AU.

**c. All authorized users (AU) are listed on license?** **[157.13(2)]** ☐ Yes ☐ No ☐ N/A

(1) If no, was as the department notified of changes to the AU list? ☐ Yes ☐ No

(2) New A.U. meets department training requirements? **[157.13(5)(b)]** ☐ Yes ☐ No ☐ N/A

**. Personnel interviewed at licensee address during the inspection.** (*attach additional sheets*)

** Indicates those individuals in attendance at exit meeting

Individual 1:

Individual 2:

Individual 3:

Individual 4:

Individual 5:

**e. Describe the licensed materials program: (type and quantities of licensed materials received, transferred, distributed, redistributed, number of facilities(customers) served, size of staff, sealed source, etc).**

(1) Licensee distribute(s). ☐ Sealed Sources ☐ Alpha and Beta emitting material
☐ Photon emitting material. ☐ Generators ☐ Iodinated material (I-131 or I-125)

(2) The license identifies all radionuclides possessed by licensee?**[L/C]** ☐ Yes ☐ No

(3) Radioactive materials in licensee possession are within quantity limits indicated on license. **[L/C]** ☐ Yes ☐ No

**Note:** Request a copy of licensee's most recent inventory of radioactive materials, including sealed sources.

(4) The licensee distributes and redistributes sealed and unsealed radioactive materials. ☐ Yes ☐ No ☐ N/A

## 4. Management Oversight:

**a. Management supports ALARA.** **[157.21(2)]** ☐ Yes ☐ No

**b. Management supports RSO efforts.** ☐ Yes ☐ No

**c. Radiation protection annual audits are being performed?** **[157.21(3)]** ☐ Yes ☐ No

(1) Audits conducted by?

(2) Scope of audit (areas of the program licensee reviewed)

(3) Audits and review records of the licensee program are being maintained. **[157.31(a)(2)]**
**Note:** These records must be kept for three years after they are made. ☐ Yes ☐ No

(4) Audits conducted at intervals not exceeding 12 months. **[157.21]** ☐ Yes ☐ No

(5) Deficiencies found in the program following a self-audit? ☐ Yes ☐ No
If yes, have the deficiencies been corrected? **Note:** The inspector should look for repeat deficiencies

(6) Records reviewed by department Inspector. ☐ Yes ☐ No

**d. Performance evaluation factors ( P.E.F.).**

(1) Senior management involved with the radiation protection program and RSO oversight. ☐ Yes ☐ No

(2) The RSO has sufficient time to perform his/her radiation safety duties. ☐ Yes ☐ No

(3) Licensee has sufficient staffing to support its activities and radiation protection programs. ☐ Yes ☐ No

(4) Adequate audits of the licensee program. ☐ Yes ☐ No
**Note:** PEF evaluations are best accomplished by interviewing management, RSO, ANP, AU and other licensee's personnel.

**5. Pharmacy Facilities:** **ch. HFS 157.28(1)**

**a. Has the facility design and/or locations of use changed?[L/C]** ☐ Yes ☐ No
**If yes, has the license been amended** ☐ Yes ☐ No
**Note:** The Inspector should request a tour of the licensee's facilities.

**b. Through observations, the areas for receiving, usage and storage of licensed materials are secured and adequate for licensee's activities.** ☐ Yes ☐ No

(1) There is a clear delineation between restricted and unrestricted areas. ☐ Yes ☐ No
Note: Check for barriers, postings, security, and contamination monitoring stations also worker's instructions.

(2) Areas assigned as receipt, use, preparation and waste storage are identified.
☐ Yes ☐ No

**c. The licensee makes reasonable efforts to maintain radiation levels (ALARA) in areas where licensed activities are performed. [157.27(2)]** ☐ Yes ☐ No

**d. Are ventilation systems (for iodination's) adequate and all required effluent dose limits met? [157.21 and L/C]** ☐ Yes ☐ No
Note: License maintains a procedure to ensure ventilation systems are working (e.x., monitoring HEPA filters weekly, Continuous monitor of HEPA filter).

**e. There are adequate numbers of lead shields (L-Blocks) in place for work being performed.**
☐ Yes ☐ No

**f. Generators are housed in a separate room.** ☐ Yes ☐ No ☐ N/A

(1) If (f) is no, are generators properly shielded and isolated to keep radiation levels ALARA?
☐ Yes ☐ No ☐ N/A

## 6. Inspection History of Licensee's Program:

**a. Is this an initial inspection?** ☐ Yes ☐ No ☐ N/A

**b. Last inspection date at this location.**

**c. List previous items of violations:**

**d. Have previous violation(s) been properly corrected?** ☐ Yes ☐ No
If no, list those violations not corrected with an explanation.

**e. List previous items of recommendations:**

**f. Did licensee address previous recommendation(s)** ☐ Yes ☐ No ☐ N/A
If no, explain.

## 7. Survey Equipment And Instrumentation:

**a. There are sufficient numbers of portable and fixed monitoring equipment and they conform to the license description.** **[L/C]** ☐ Yes ☐ No

(1) Do survey meters meet the department's criteria? **[157.25(1)]** ☐ Yes ☐ No

(2) Calibration records are being maintained for each fixed and portable monitor? **[157.13(3)]** ☐ Yes ☐ No

(3) Annual calibrations of licensee's equipment are being performed in-house or by a licensed Vendor(s).
☐ In-house ☐ Authorized outside Vendor(s) ☐ N/A
**Note:** Make list of monitoring equipment, check and record all pertinent information pertaining to the instrument calibrations, serial #, etc.

**c. Procedures are in place to identify, evaluate, and report equipment safety component defects? Records are kept for 5 years.** **[10cfr21.21]** ☐ Yes ☐ No
Note: Inquiry about basic components of licensee's equipment where a failure or defect have been founded. If these findings are left unattended; they could become substantial safety hazards.

**d. Dose Calibrators for Photon-emitters.** **[157.13(4)]** ☐ N/A

(1) Constancy checked each day prior to assay of patient dosages. ±10% ☐ Yes ☐ No
**Note:** Dedicated check source for this procedure must be used.

(2) Linearity checked at installation and quarterly. ±10% ☐ Yes ☐ No

(3) Geometry dependence checked at installation. ± 10% ☐ Yes ☐ No
**Note:** Must be checked against volumes and configurations. (volumes dispense and syringe sizes)

(4) Accuracy checked at installation and yearly. ±10% ☐ Yes ☐ No
Note: If the dose calibrator has been repaired, relocated or adjusted, all appropriate tests listed above must be repeated, and be within ± 10% accuracy before putting the calibrator back in use.

**e. Dose measurements for Beta- and Alpha-Emitters. [157.13(4)]** ☐ N/A

(1) Calibrated with each isotope being used by licensee. ☐ Yes ☐ No

(2) Constancy checked each day prior to assay of patient dosages. ± 10% ☐ Yes ☐ No

(3) Geometry dependence checked at installation. ± 10% ☐ Yes ☐ No

(4) Accuracy checked at installation and yearly. ±10% ☐ Yes ☐ No

(5) Linearity checked at installation and quarterly. ±10% ☐ Yes ☐ No

(6) Dose measurement procedure available and in use. **[L/C]** ☐ Yes ☐ No
Note: If the calibrator is repaired, adjusted or relocated, all tests mentioned above must be repeated. If any test exceeds +/- 10% the calibrator must be repaired or replaced.

Note: Equipment Safety Component Defects: Are procedures in place to identify, evaluate, and report equipment safety component defects? [refer to 10 CFR 21.21, voluntary report to ***DHFS***] Records are kept for 5 years. Inquire about basic components of licensee's equipment where a failure or defect has been found. If these failures or defects are left unattended; they could become substantial safety hazards.

## 8. Surveys And Contamination Control: ch. HFS 157.25(1)

**a. Are routine surveys being performed for radiation levels and removable contamination? [L/C]** ☐ Yes ☐ No

(1) Are area ambient surveys being performed daily and records maintained? **[157.31(3)(b)]** ☐ Yes ☐ No

(2) Are contamination surveys being performed and records maintained? **[157.31(3)]** ☐ Yes ☐ No

(3) Surveys of radiopharmaceutical preparation area after each run. **[L/C]** ☐ Yes ☐ No

(4) Weekly surveys for storage and unrestricted areas? **[L/C]** ☐ Yes ☐ No

**b. Is proper equipment being used to detect contamination and measure radiation levels?** **[L/C]** ☐ Yes ☐ No

(1) List meter(s) used for ambient radiation level surveys. **Note:** check meter type, model, serial #, calibration records and batteries.

(2) Identify instrument used for detecting removable contamination. **Note:** check instrument type, model, serial #, calibration records.

**c. Corrective actions are being implemented and documented when excess radiation or contamination levels are detected.** ☐ Yes ☐ No

(1) Action level for radiation levels established and used? **[L/C]** ☐ Yes ☐ No

(2) Action level for removable surface contamination established and used? **[L/C]** ☐ Yes ☐ No

## 9. Sealed Source and Leak Test: ch. HFS 157.24

**a. Leak test performed on each sealed source at 6 months intervals or as specified in SSD Certificate?** **[157.24(1)(a)2]** ☐ Yes ☐ No

(1) Leak test performed as described in the license. **[L/C]** ☐ Yes ☐ No

(2) Leak test records are being maintained for three years. ☐ Yes ☐ No

(3) Any source found leaking? If yes, was the department notified? ☐ Yes ☐ No ☐ N/A

**b. Records are available showing receipts of each sealed source. [157.31]** ☐ Yes ☐ No

**c. Sealed sources are physically inventoried every six-month interval.** ☐ Yes ☐ No

## 10. Radioactive Materials Use And Control:

**a. Radioactive materials stored in an unrestricted area are secured from unauthorized access to or removal from the area? [157.28(1)(a)]** ☐ Yes ☐ No ☐ N/A

**b. Radioactive materials in a controlled unrestricted area, but not in storage, are under surveillance at all times? [157.28(1)(b)]** ☐ Yes ☐ No ☐ N/A

**c. Are procedures available for receiving and opening packages? [157.29(6)]** ☐ Yes ☐ No

**d. Restricted and unrestricted areas are delineated?** ☐ Yes ☐ No

**e. Licensed radioactive materials are only transferred to authorized recipients? [157.13(15); .13(4)(g); .13(4)(I); & .13(4)(k)]** ☐ Yes ☐ No

(1) Records of receipt and transfer of radioactive materials are maintained? ☐ Yes ☐ No
Note: Review licensee's most current inventory. **[157.06(1) & .13(18)]**

**11. Instructions to workers:** **ch. HFS 157.88(2)**

**a. All individuals / workers who are likely to receive an occupational radiation dose [>1mSv(100mR)/year] are kept informed of their exposures.** **[157.88(2)(a)]** ☐ Yes ☐ No

(1) Annual training is provided to employees who will or projected to exceed 100 mR/year. **[157.88(2)]** ☐ Yes ☐ No

(2) Required records maintained for three year. **[157.88(3)(b)]** ☐ Yes ☐ No

**b. Other workers given training as needed?** **[157.13.(2)] [L/C]** ☐ Yes ☐ No
Note: (e.g.; radiopharmacy technicians, courier/drivers of licensee's delivery vehicle, and ancillary personnel.)

(1) Training records maintained and available for department review. ☐ Yes ☐ No ☐ N/A

(2) Workers are knowledgeable of applicable parts of ch. HFS 157 " Radiation Protection", license conditions and licensee's operation and emergency procedures. ☐ Yes ☐ No

**c. Hazmat training provided for transportation personnel.** ☐ Yes ☐ No ☐ N/A
(e.g; courier/drivers of licensee's delivery vehicle) **[49cfr172.700]**

**12. Staff Training Program:**

**a. List personnel trained to do specialized services, such as instrument calibrations, and leak testing.** **[L/C]** ☐ Yes ☐ No

**b. Training course approved by the department. (Appendix G, WisRegs)** ☐ Yes ☐ No ☐ N/A

(1) Instructor's name and qualifications.

(2) List subjects/topics covered:

(3) List individuals who are trained as an authorized user. **Note:** Request training records for each authorized user.

**c. List all trained personnel that have been approved in writing by the RSO.** **[L/C]** ☐ Yes ☐ No

(1) Documentation of training. ☐ Yes ☐ No

(2) Inspector observed AU performing licensee's activities. ☐ Yes ☐ No ☐ N/A

(3) Individual(s) authorized to perform **Non-Routine** maintenance on dose calibrators. ☐ Yes ☐ No ☐ N/A

If yes, list the individual(s) and review the documented training and procedures used.

(4) The AU is knowledgeable and familiar with licensee's operating and emergency procedures? ☐ Yes ☐ No

(5) Were there any incidents involving radioactive material since last inspection? ☐ Yes ☐ No ☐ N/A

## 13. Notification and Reports: ch. HFS 157.32(2)

**a. Did the licensee provide monitored users, with an annual written report of their occupational exposure?** **[157.88(3]** ☐ Yes ☐ No ☐ N/A

(1) Occupational radiation exposure reports for badged personnel are being maintained? ☐ Yes ☐ No

(2) At termination of employment, are worker's exposure records available to he/she upon request? **[157.88(3)(c)]** ☐ Yes ☐ No

**b. Has any theft or loss of licensed material occurred since the last inspection?** **[157.32(1)]** ☐ Yes ☐ No

**c. Has there been any reportable incident since last inspection?** **[157.32(2)] & [.13(17)]**
If yes, describe the root cause and corrective actions taken. ☐ Yes ☐ No

**d. Has any occupational overexposure and/or excessive levels of radiation been reported to the department?** **[157.32(3)]** ☐ Yes ☐ No

**e. The RSO and all authorized users are aware of and have access to the department's emergency telephone number. Note:** Dept 24-hour emergency # (608) 258 0099 ☐ Yes ☐ No

(1) What was the root cause? Was the department notified?

**g. Any report(s) of leaking source(s) made to the department since last inspection?** **[157.37(7)]** ☐ Yes ☐ No

## 14. Posting and Labeling: ch. HFS 157.88 and .29(2)

**a. Is posting required?** **[157.29(3)(d)]** ☐ Yes ☐ No
Note: "Caution – Radioactive Material" sign may not be posted if the levels are less than 0.05 Sv (5 mR/hr) at 30 cm from the container surface.

(1) "Caution- Radioactive Material" signs posted where required. **[157.29(2)(e)]** ☐ Yes ☐ No ☐ N/A

(2) "Caution Radiation Area" sign posted as required. **[157.29(2)(a)]** ☐ Yes ☐ No ☐ N/A

(3) All transport radioactive material containers are labeled and legible. **[157.29(4)]** ☐ Yes ☐ No

**b. The department's "Notice to Employee" posted in an appropriate area.** **[157.88(1)(a)7]** ☐ Yes ☐ No

**c. The department's rules, license and licensed conditions, notice of violation(s) and applicable sections of Chapter HFS 157 are posted, or a notice of availability is posted for the employee's review.** **[157.88(1)(b)]** ☐ Yes ☐ No

**d. Are there any exemptions to posting [157.29(3)] or labeling [157.29(4)] requirements?** ☐ Yes ☐ No ☐ N/A

## 15. Independent and Confirmatory Measurements:

**a. Inspector performed independent surveys.** ☐ Yes ☐ No

**b. Survey instrument used:**

(1) Mfg / Make:
(2) Model #:
(3) Serial #:
(4) Last calibration date:

**c. Licensee survey instrument(s): (if compared)**

(1) Mfg. / Make:
(2) Model #:
(3) Serial #:
(4) Last calibration date:

**d. Describe inspector instrument readings as compared to licensee instrument readings.**

**e. Independent readings**

(1) Highest radiation level in unrestricted areas. **(mR)/hr**

(2) Highest radiation level in restricted areas. **(mR)/hr**

**f. Radiation levels in all unrestricted areas do not exceed 2mR/hr in any one-hour or 100mr in a year.** **[157.23(1)]** ☐ Yes ☐ No

**g. Reading at external surface of transportation containers.** **(mR)/hr**
**[10 CFR 71.47]**

**16. Personnel Monitoring:**

**a. Dosimetry required?** **[157.25(2)(a) 6] [L/C]** ☐ Yes ☐ No

**b. Dosimeters are provided to workers.** ☐ Yes ☐ No

(1) Type. ☐ Film ☐ TLD ☐ Extremity ☐ Whole Body ☐ Other _

(2) Frequency of reports. ☐ Weekly ☐ Monthly ☐ Quarterly

(3) Film / TLD supplier.

(4) NVLAP certified **[157.25(1)(c) 2]** ☐ Yes ☐ No

**c. Monitoring reports reviewed by licensee.** **[L/C]** ☐ Monthly ☐ Quarterly ☐ Semi-annually
Note: Identify and record the reviewer.

**d. Personnel monitoring records are available for review.** ☐ Yes ☐ No

(1) Monitoring results are reported in Sv or Rem. **[157.31(1)]** ☐ Yes ☐ No

**e. Reviewed personnel monitoring records, from** **to**

(1) Max. DDE _____ mSv _____ ( mR) ☐ Monthly ☐ Quarterly ☐ Annually

(2) Max. SDE _____ mSv _____ ( mR) ☐ Monthly ☐ Quarterly ☐ Annually

**f. Did any worker's occupational dose exceed the regulatory limits?** ☐ Yes ☐ No
**[157.2(1)(a)]**

**g. Are there unmonitored workers whose job has changed since last inspection?** ☐ Yes ☐ No

(1) Did the change in job activity put the worker above the 10% occupational dose limit? ☐ Yes ☐ No

**h. Are records of personnel exposure, surveys and monitoring evaluation retained?** ☐ Yes ☐ No
Note: Records until the department terminates license.

**i. If a worker declared her pregnancy, did licensee comply with [157.22(8)] & [157.31(7)]?** ☐ Yes ☐ No

**17. Radioactive Waste Management:** **ch. HFS 157.30(1)**

**a. Storage area properly secured.** **[157.28(1)(a)]** ☐ Yes ☐ No

**b. Storage area(s) properly posted.** **[157.29(2)]** ☐ Yes ☐ No

**c. Waste containers properly labeled.** **[157.29(4)]** ☐ Yes ☐ No

**d. Decay-in-storage is approved and procedures are being followed.** ☐ Yes ☐ No
**[157.30(6)]& [157.62(1)] [L/C]**

(1) Radionuclides that are being stored, all have half-lives less than 120 days. ☐ Yes ☐ No

(2) Radionuclides are segregated for storage according to their half-life. ☐ Yes ☐ No ☐ N/A

(3) Each nuclide in waste storage is stored for a minimum of 10 half-lives. ☐ Yes ☐ No

**e. Before waste is disposed of, surveys are performed at the surface of each container with the survey meter set to its most sensitive scale.** ☐ Yes ☐ No

**f. Waste received from customers are surveyed and checked for removable contamination.**
Note: Any contaminate readings of 200 mR or above must be reported to the department. ☐ Yes ☐ No

**g. Effluents from license materials are maintained ALARA.** ☐ Yes ☐ No

(1) The fume hood is being checked for adequate airflow. ☐ Yes ☐ No ☐ N/A

(2) Filters are being maintained and replaced according to the manufacturer's instructions and licensee's written procedures. **[L/C]** ☐ Yes ☐ No

**h. Records of disposal are maintained.** ☐ Yes ☐ No

## 18. Transportation of Radioactive Material: ch. HFS 157.29(3); 10 CFR 71 and 49 CFR 171 - 178

**a. Licensee makes shipments of radioactive material. [157.92(1)]** ☐ Yes ☐ No

(1) Security and all applicable regulations followed. **[157.92(3)]** ☐ Yes ☐ No

**b. Shipments are made to common carriers. [157.92(2)]** ☐ Yes ☐ No

**c. Shipments are transported in licensee private vehicle(s). [157.92(3)]** ☐ Yes ☐ No

(1) Driver trained in HAZMAT communications, including loading and unloading radioactive materials. **[49cfr 177.816 & .842]** ☐ Yes ☐ No

**d. No shipments made since last inspection.** ☐ Yes ☐ No

**Note: To be completed if shipments were made since last inspection. (e. through g.)**

**e. Licensee package and ship radioactive materials according to regulatory procedures.** **[157.94]** ☐ Yes ☐ No

**f. Type A package used for shipping and marked "Type A".** ☐ Yes ☐ No **[157.94(1)(a)]**

(1) Shipping container normally use to transport radioactive materials.
☐ Steel "Ammo" Box ☐ Aluminum Suitcase ☐ Other

**g. Package / container meets design requirements.** ☐ Yes ☐ No **[49cfr173.410 & .415]**

(1) DOT 7A or other authorized packages used for shipping. ☐ Yes ☐ No **[49cfr173.415(a)]**

(2) Package properly marked with two labels that include proper shipping name and identification number ("Radioactive material, N.O.S., UN 2928") ☐ Yes ☐ No

(3) Those packages containing more than 10 mCi of Iodinated byproduct must include the letters RQ (Reportable Quantity). ☐ Yes ☐ No

(4) Activity per package does not exceed A-1 or A-2 limit. ☐ Yes ☐ No **[49cfr173.424]**

(5) Only shipping labels " Radioactive White-1 or Radioactive Yellow-II used.
Note: Yellow-II labels must include the TI (Transport Index). **[49cfr173.424(d)]** ☐ Yes ☐ No

(6) Radiation levels at the external surface of the package for white-I labels are less than or equal to 0.5mR/hr. **[49cfr173.441]** ☐ Yes ☐ No

(7) Radiation levels at the external surface of the package for yellow II labels are greater than 0.5 mR/hr but does not exceed 50 mR/hr. ☐ Yes ☐ No

(8) Contamination levels at surface of package are checked before shipping and on return from customers. ☐ Yes ☐ No

(9) All proper shipping requirements are met. **[49cfr172.200-204]** ☐ Yes ☐ No

(10) Emergency procedures and response telephone number(s) available. **[49cfr172.201(d)]]** ☐ Yes ☐ No

(11) Shipping papers are readily accessible during transportation. ☐ Yes ☐ No **[49cfr17177.842(d)]**

**Note:** Papers must be placed in pocket in the door of the driver's side or placed on the passenger seat. If there is no pocket, the driver must place the papers on the driver's seat when he/she is out of the vehicle.

(12) Special form materials are shipped. ☐ Yes ☐ No ☐ N/A

(13) Vehicle placarded as required. (yellow III, if TI> 1.0). ☐ Yes ☐ No ☐ N/A **[49cfr172.504(a)]**

(14) The radioactive materials are secured and properly blocked and braced in transport vehicle. **[49cfr177.834(a) & .842]** ☐ Yes ☐ No

(15) A QA program for packaging is in place. **[L/C]** ☐ Yes ☐ No

**19. License Conditions / Tie-downs:**

**a. All license conditions reviewed by department Inspector.** ☐ Yes ☐ No

b. Licensee activities are being conducted in accordance with license conditions. ☐ Yes ☐ No

**20. Bulletins and Information Notice:**

a. Licensee is receiving the department information notices and bulletins. ☐ Yes ☐ No

b. Licensee has taken appropriate action in response to the bulletins and notices. ☐ Yes ☐ No

**21. Exit Meeting at Conclusion of Inspection:**

a. Identify and list the individuals in attendance.

b. List those issues discussed at exit meeting.

**22. Summary of Violations and Recommendations:**

# 7

# STATE OF WISCONSIN
# HEALTH AND FAMILY SERVICES

## Radiation Protection Section

**Radiation Protection Procedure No. 4.01**

**Management of Allegations**

**Prepared By:**_____**Date**_____

**Reviewed By:**_____**Date**_____
**Cheryl K. Rogers, Materials Program Supervisor**

**Reviewed By:**_____**Date**_____
**Mark C. Bunge, X-Ray Program Supervisor**

**Approved By:**_____**Date**_____
**Paul S. Schmidt, Radiation Protection Section Chief**

**Effective Date:**_____

## Table of Contents

## 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. Informs the Bureau Director of the allegations and proposed actions to be taken in response to the allegations, authorizes the release of the identity of alleger(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 alleger'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 Attachment 4.01-1 information as possible from alleger.

3.1.2 If the allegation involves discrimination under Section 211 of the Energy Reorganization Act (age, sex, race, etc.), then refer the alleger to the Equal Rights Division in the Department of Workforce Development.

3.1.3 If the alleger refuses to provide his/her name or other form of identification, then obtain as much Attachment 4.01-1 information as possible and advise the alleger 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 alleger 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 Alleger's Identity.

**Note:** All reasonable efforts to maintain confidentiality of the alleger's identity will be made, however, the RPS cannot guarantee confidentiality. Disclosure of an alleger'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 alleger, inform the alleger of the degree to which their identity can be protected, including the following:

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

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

- The alleger 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 in furtherance of a wrongdoing investigation, including an investigation of a discrimination allegation
- Disclosure is necessary to support a hearing on an enforcement matter
- The alleger has taken actions that are inconsistent with and override the purpose of protecting the alleger's identity

- Disclosure is mandated by Wisconsin's Open Records law.

3.2.3 If the alleger'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 alleger's identity is known, then inform the alleger, 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 alleger, then inform the alleger 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 first and 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 alleger or confidential source?
- Has the alleger 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 Alleger

**Note:** The Program Supervisor or designated staff shall be responsible for informing the alleger 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 alleger or confidential source of the intent to refer.

- Provide the initial notification to the alleger by phone and document with a letter to the alleger. Include in the notification that the RPS will evaluate the licensee's or registrant's activities and response and that the alleger or confidential source will be informed of the final disposition of the allegation.

- If the alleger or confidential source cannot be reached by telephone, then inform the alleger or confidential source by letter of the intent to refer the allegation to the licensee.

- If the alleger 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 alleger or confidential source, or any information that could result in the licensee or registrant identifying the alleger 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 alleger or confidential source in the written referral to the licensee or registrant, unless written permission from the alleger 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 the least, 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 alleger 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 the following techniques:

  - inspect the issue not the alleger or confidential source,

  - avoid prejudgment,

  - do not communicate that the specific issue was raised by an alleger 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, and

  - 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): a secure file that contains the hardcopy documentation concerning the allegation.

### 4.2 Computer Based

The Allegation Management System (AMS) 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 Alleger**

DEPARTMENT OF HEALTH AND FAMILY SERVICES
Division of Public Health
Radiation Protection Section
Attachment 4.01-1 (3/02)

STATE OF WISCONSIN

# 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 :

ADDITIONAL COMMENTS:

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:

(I) 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 alleger 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 alleger 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 alleger 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 alleger and other sensitive information are outlined below.

1) Restrict staff discussions to those individuals who truly need-to-know. The alleger'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 alleger'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 alleger 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 alleger. The information should be re-worded to reflect the basic facts and remove any language that could be used to identify the alleger.

**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:** _____ **Date:** _____
??

**Reviewed By:** _____ **Date:** _____
**Cheryl K. Rogers, Materials Program Supervisor**

**Approved By:** _____ **Date:** _____
**Paul Schmidt, Radiation Protection Section Chief**

**Effective Date:** _____

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

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

### 2.2 Radiation Protection Section Staff

- 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.
- Takes the lead role in response to incidents involving radioactive materials and coordinates with the MPS.
- Participate on and coordinate 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.

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

e. A multi-channel analyzer if the situation may require a field identification of unknown isotopes.
f. Personally assigned dosimetry and a direct reading dosimeter.
g. Camera
h. Cellular phone.
i. 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.
- 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 (Phone Number).
- If no owner can be found, notify EPA (Phone Number) 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 prepares 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 supplies used in the 'response kit' with inventory 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 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
## 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

# 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
# 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?