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MEMORANDUM FOR: B. Paul Cotter, Jr.
Chief Administrative Judge
Atomic Safety and Licensing Board Panel

FROM: *John C. Hoyle*
John C. Hoyle, Acting Secretary

SUBJECT: REQUEST FOR HEARING SUBMITTED BY
KELLI J. HINDS

Attached is a request for hearing dated May 27, 1994 and submitted by Kelli J. Hinds (IA 94-12) in response to an "Order Prohibiting Involvement In Licensed Activities (Effective Immediately)" issued by the NRC Staff. The Order was issued on May 23, 1994 and published in the Federal Register at 59 Fed. Reg. 28433 (June 1, 1994). (Copy Attached)

The request for hearing is being referred to you for appropriate action in accordance with 10 C.F.R. Sec. 2.772(j).

Attachments: as stated

cc: Commission Legal Assistants
OGC
CAA
OPA
EDO
NMSS
Kelli J. Hinds

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To Whom It May Concern:

I am formally requesting a hearing based on the documents I received from the Nuclear Regulatory Commission dated the 23rd of May, 1994.

OFFICE OF SECRETARY
SECRETARY & SERVICE
BRANCH

I do not, nor have I ever denied the charges placed against me. There is, however, pertinent information that I would like to have heard on my behalf. I was involved in the activities described in this letter, however, nothing was mentioned as to the reason why.

I was specifically instructed by my supervisor; as were all the other technologists, not to use the plus or minus 10% rule that we all knew existed from the NRC. I personally was called into my supervisor's office with a verbal warning not to document over 5.0 mCi, which would have been allowed by the NRC (I had recorded a dose of 5.2 mCi). I believed it was a condition of employment, so I did as I was instructed.

When I became acting supervisor for this same department in December of 1992, I was specifically instructed by Ball Memorial Hospital Administration not to go in and upset the department, just continue on with the previous practices. I then began to instruct the new technologists as I had been previously instructed. (The other technologists were already trained in the "old" way by our previous supervisor. This was our departmental practice by now).

It is not my intent to show myself innocent or without fault - that has never been my stand. I was the first person to testify during the investigation and was willing to help the NRC in any way I could. I showed them ways to detect false documentation as well as how to calculate obvious overdosing by others as well as myself.

I guess what I'm trying to say is that I feel that these consequences you have given me are too severe. I have been unable to work in the Nuclear Medicine community since I was fired by Ball Memorial Hospital in September of 1993, so, it is unlikely that I will be employed in the field anytime soon anyway. I feel that some punishment may be necessary, but to take away my livelihood for the next three years is too harsh a punishment for an honest, cooperative person.

Sincerely,

Kelli J. Hinds

For The Nuclear Regulatory Commission
Theodore R. Quay,
*Director, Project Directorate IV-3, Division
of Reactor Projects—III/IV, Office of Nuclear
Reactor Regulation.*
[FR Doc. 94-13249 Filed 5-31-94; 8:45 am]
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[A 94-12]

**Kelli J. Hinds; Muncie, Indiana; Order
Prohibiting Involvement In Licensed
Activities (Effective Immediately)**

I

Ball Memorial Hospital, Muncie, Indiana (Ball or Licensee) is the holder of Byproduct Material License No. 13-00951-03 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR parts 30 and 35. The license authorizes the use of byproduct material for medical purposes pursuant to 10 CFR part 35 (e.g., as radiopharmaceuticals identified in 10 CFR 35.100, 35.200 and 35.300; as brachytherapy sources identified in 10 CFR 35.400; as sealed sources identified in 10 CFR 35.500; and as prepackaged in vitro kits identified in 10 CFR 31.11). The facility where licensed materials are authorized for use and storage is located at 2401 University Avenue, Muncie, Indiana. The license, originally issued on August 19, 1958, was last amended on February 24, 1994. The license was due to expire on December 31, 1993, but continues in effect pursuant to 10 CFR 30.37(b).

Ms. Kelli J. Hinds was employed by Ball from October 17, 1988, until her employment was terminated by Ball effective September 23, 1993. She most recently held the position of Acting Chief Nuclear Medicine Technologist at Ball with responsibilities involving compliance with NRC requirements for the use of byproduct materials.

II

On July 19, 1993, the NRC Region III Office received information from an individual outside of the Licensee's organization that the Licensee was investigating an allegation that it received from one of its nuclear medicine technologists in early June 1993. NRC contacted the Licensee to verify the information and determined that, allegedly, the Acting Chief Nuclear Medicine Technologist at Ball Memorial Hospital, Ms. Kelli J. Hinds, had increased the dosages of radiopharmaceuticals used in nuclear medicine diagnostic studies in order to reduce the imaging time and had falsified the records of the dosage measurements. In mid-June 1993,

during the Licensee's investigation, Ms. Hinds admitted that she increased the dosages of radiopharmaceuticals given to patients for nuclear medicine diagnostic studies in order to minimize a patient's discomfort, to reduce the duration of a study of a critically ill patient, or to enhance the clarity of the image for a study performed on an obese patient. Based on the Licensee's investigation, the Licensee terminated Ms. Hinds' employment on September 23, 1993.

The NRC commenced an inspection on July 21, 1993, and determined that, for approximately 10 percent of the lung, liver, bone and gastrointestinal tract imaging studies using technetium-99m and xenon-133 that she performed between October 1988 to June 1993, Ms. Hinds increased the dosages of the radiopharmaceutical by as much as 40 percent above the approved dosage ranges without authorization from a physician authorized user. Further, Ms. Hinds entered false information in the dosage measurement records (i.e., dosages within the approved range were indicated in the records even though the actual administered dosages were higher). In addition, even after Ms. Hinds became Acting Chief Nuclear Medicine Technologist in December 1992, she stated that she requested and received approval from the Radiation Safety Committee to increase dosage amounts for various studies but continued to administer dosages greater than the authorized quantities without physician approval and recorded false information. As a result of the NRC inspection, a Confirmatory Action Letter (CAL) was issued to the Licensee on July 26, 1993, and a Confirmatory Order was issued to the Licensee on October 20, 1993 (EA 93-215). The CAL and Order documented specific procedures and verifications to prevent any further unauthorized increases in patient dosages.

The NRC Office of Investigations (OI) is conducting an investigation of this matter. While the investigation has not been completed, the available information establishes that, since 1988, Ms. Hinds deliberately increased the dosages of NRC-licensed materials used in certain nuclear medicine procedures and attempted to conceal the increase in the dosage by falsifying the dosage measurement records. In a transcribed sworn statement on September 1, 1993, Ms. Hinds stated that she was aware of the authorized radiopharmaceutical dosage limits at Ball and she admitted that, since 1988, she has increased the dosage of radiopharmaceuticals given to some patients without express authorization from a physician

authorized user and that she falsified the records of those radiopharmaceutical dosage measurements. Although the NRC investigation is continuing, the following significant violations have been identified to date:

A. Ms. Hinds' deliberate actions caused the Licensee to be in violation of 10 CFR 35.25(a)(2) in that Ms. Hinds failed to follow the instructions of the supervising physician authorized users as contained in the Licensee's procedure, "Approved Dose Ranges of Radiopharmaceutical Use." That procedure specifies the radioisotope, procedures and dosage ranges to be used. Ms. Hinds intentionally increased the dosages beyond the range prescribed by the procedure.

B. Ms. Hinds' deliberate actions caused the Licensee to be in violation of License Condition No. 16, which requires the Licensee to implement the model safety rules published in NRC Regulatory Guide 10.8, appendix I, item 14. Item 14 requires that each patient dosage be assayed in the dose calibrator and prohibits the use of a dosage if it is more than 10 percent off from the prescribed dosage. Ms. Hinds indicated that she increased some patient dosages by 10-40%.

C. Ms. Hinds' deliberate actions caused the Licensee to be in violation of 10 CFR 30.9(a), which requires that records required to be maintained by a licensee be complete and accurate in all material respects. More specifically, 10 CFR 35.53(c) requires that records of the measurement of radiopharmaceutical dosages contain certain information, including the prescribed dosage and activity of the dosage at the time of measurement. Ms. Hinds admitted that from October 1988 to June 1993, she increased the activity of some radiopharmaceutical dosages after the initial assay was performed and she did not enter into the dosage measurement records the actual activity of the radiopharmaceutical that was given to some patients. Rather, she entered an activity level which was within the dosage range prescribed by the physician authorized user at Ball.

The deliberate actions described in A-C above caused Ms. Hinds to be in violation of 10 CFR 30.10(a)(1), which requires in part that any employee of a licensee may not engage in deliberate misconduct that causes or, but for detection, would have caused, a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Commission.

III

As the Licensee's Acting Chief Nuclear Medicine Technologist from approximately December 1992 through June 1993, Ms. Hinds supervised the other nuclear medicine technologists employed by Ball and Ms. Hinds was responsible for ensuring that the Commission's rules, regulations, and license conditions in her area of responsibility were met and the records that were created to demonstrate compliance with the Commission's rules, regulations, and license conditions were true and accurate in all material respects.

As set forth above, Ms. Hinds engaged in deliberate misconduct from October 1988 through June 1993, by increasing the dosages of radiopharmaceuticals given to patients at Ball Memorial Hospital without first receiving the approval of a physician authorized user as required by the Commission's regulations. Ms. Hinds further engaged in deliberate misconduct by entering false information into the dosage measurement records for the dosages actually given to patients. These actions constitute violations of 10 CFR 30.9, 35.25(a)(2), 35.53, and Condition No. 16 of NRC Byproduct Materials License No. 13-00951-03 on the part of the Licensee; and violations of 10 CFR 30.10 on the part of Ms. Hinds.

Consequently, I lack the requisite reasonable assurance the NRC-licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected, if Ms. Hinds is permitted at this time to supervise or otherwise reengage in licensed activities. Therefore, the public health, safety and interest require that Ms. Hinds be prohibited from being involved in any NRC-licensed activities for a period of one year from the date of this Order. In addition, for a three year period from the date of the Order, the public health, safety and interest require that Ms. Hinds be required to:

- (1) Provide a copy of this Order to any prospective employer who engages in NRC-licensed activities at the time that Ms. Hinds solicits or begins negotiating employment with such prospective employer. The purpose of this notice is so that any prospective employer is aware of Ms. Hinds' prohibition from NRC-licensed activities for a period of 1 year from the date of this Order and so that any prospective employer is aware of the Order prior to making a decision regarding Ms. Hinds employment in NRC-licensed activities for a period of 2 years following the 1 year prohibition from NRC-licensed activities, and (2)

notify the NRC of the acceptance of employment involving NRC-licensed activities to assure that the NRC can monitor the status of Ms. Hinds' compliance with the Commission's regulatory requirements. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR part 30, and 10 CFR part 35, It Is Hereby Ordered, Effective Immediately, That:

A. Ms. Kelli J. Hinds is prohibited from engaging in NRC-licensed activities for a period of one year from the date of this Order. NRC-licensed activities are those activities which are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

B. For a period of three years from the date of the Order, Ms. Hinds shall:

1. Provide a copy of this Order to any prospective employer who engages in NRC-licensed activities (as defined in A above) at the time that Ms. Hinds solicits or begins negotiating employment with such prospective employer. The purpose of this requirement is to ensure that all prospective employers are aware of Ms. Hinds' prohibition from engaging in NRC-licensed activities for a period of 1 year from the date of this Order and are aware of the Order prior to making a decision regarding Ms. Hinds' employment in NRC-licensed activities for a period of 2 years following the 1 year prohibition from NRC-licensed activities.

2. With 20 days of her acceptance of an employment offer involving NRC-licensed activities, or her becoming involved in NRC-licensed activities, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer or the entity where she is, or will be, involved in the NRC-licensed activities.

C. If Ms. Hinds is currently involved in NRC-licensed activities at any employer or entity, Ms. Hinds shall, in accordance with Paragraph IV.A above, immediately cease involvement in the NRC-licensed activities and, within 20 days of the date of this Order, provide

notice to the Director, Office of Enforcement, at the address in Paragraph IV.B.2 above, of the name, address, and telephone number of the employer or entity where the licensed activities were being conducted.

The Director, Office of Enforcement, NRC, may, in writing, relax or rescind any of the above conditions upon demonstration by Ms. Hinds of good cause.

V

In accordance with 10 CFR 2.202, Ms. Kelli J. Hinds must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Ms. Hinds or other persons adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555; to the Assistant General Counsel for Hearings and Enforcement at the same address; to the Regional Administrator, Region III, U.S. Nuclear Regulatory Commission, 801 Warrenville Road, Lisle, Illinois 60532-4351; and to Ms. Hinds, if the answer or hearing request is by a person other than Ms. Hinds. If a person other than Ms. Hinds request a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Ms. Hinds or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Ms. Hinds, or any person adversely affected by this Order, may in addition to demanding a hearing, at the time that answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere

suspicion, unfounded allegations, or error.

In the absence of any request for a hearing, the provisions specified in section IV above shall be final 20 days from the date of this Order without further order or proceedings. An Answer or a Request for a Hearing Shall Not Stay the Immediate Effectiveness of This Order.

For The Nuclear Regulatory Commission
Dated at Rockville, Maryland, this 23rd day of May 1994.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear
Materials Safety, Safeguards and Operations
Supports

[FR Doc. 94-13251 Filed 5-31-94; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-316]

Indiana Michigan Power Co. (DC Cook 2); Exemption

I

Indiana Michigan Power Company (the licensee) is the holder of Facility Operating License No. DPR-74 which authorizes operation of the Donald C. Cook Unit 2 Nuclear Plant at steady-state reactor power levels not in excess of 3411 megawatts thermal. The Cook 2 facility is a pressurized water reactor located at the licensee's site in Berrien County, Michigan. The license provides, among other things, that it is subject to all rules, regulations, and Orders of the Nuclear Regulatory Commission (the Commission) now or hereafter in effect.

II

Section 50.54(o) of 10 CFR part 50 requires that primary reactor containments for water cooled power reactors be subject to the requirements of appendix J to 10 CFR part 50. Appendix J contains the leakage test requirements, schedules, and acceptance criteria for tests of the leak tight integrity of the primary reactor containment and systems and components which penetrate the containment.

Paragraph III.D.2.(a) of appendix J to 10 CFR part 50 requires, in part, that Type B tests, except tests for air locks, shall be performed during reactor shutdown for refueling, or other convenient intervals, but in no case at intervals greater than 2 years. Type B tests are intended to detect local leaks and to measure leakage across each pressure-containing or leakage-limiting boundary for certain reactor containment penetrations.

Paragraph III.D.3. of appendix J to 10 CFR part 50 requires that Type C tests

shall be performed during each reactor shutdown for refueling but in no case at intervals greater than 2 years. Type C tests are intended to measure containment isolation valve leakage rates for certain containment isolation valves.

Pursuant to 10 CFR 50.12(a), the NRC may grant exemptions from the requirements of the regulations (1) which are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security; and (2) where special circumstances are present.

III

By letter dated March 9, 1994, and supplemented April 13, 1994, the licensee requested a one-time exemption from the requirements of 10 CFR part 50, appendix J, III.D.2.(a) and III.D.3 for a period of 150 days for the testing of Type B and C penetrations.

The underlying purpose of the requirement to perform Type B and C containment leak rate tests at intervals not to exceed 2 years is to ensure that any potential leakage pathways through the containment boundary are identified within a time span that prevents significant degradation from continuing or being unknown, and long enough to allow the tests to be conducted during scheduled refueling outages. This interval was originally published in appendix J when refueling cycles were conducted at approximately annual intervals and has not been changed to reflect 18-month or 2-year operating cycles. It is not the intent of the regulation to require a plant shutdown solely for the purpose of conducting the periodic leak rate tests. Based on historical data at Cook any incremental increase in leakage because of the extension would be expected to be small. Corrective actions taken for several Type C valves that were found with excessive leakage in 1992 provide increased assurance that these components will perform their safety function. In addition, recent as-found leak rates, which were only a small fraction above the previous as-left leak rates, have been 30 percent of the established reference leak rates. Therefore, since the extension is relatively short compared to the 2-year test interval requirement, it is unlikely that substantial degradation of the containment components leading to the failure of the containment to perform its safety function would occur. As a result, the application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule.

IV

Based on the above, the NRC staff has concluded that the licensee's proposed increase of the 2-year time interval for performing Type B and C containment leak rate tests will not present an undue risk to the public health and safety and is consistent with the common defense and security. The NRC staff has determined that there are special circumstances present, as specified in 10 CFR 50.12(a)(2), such that application of 10 CFR part 50, appendix J, sections III.D.2.(a) and III.D.3. are not necessary in order to achieve the underlying purpose of this regulation.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, this exemption as described in section III above is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further determines that special circumstances as provided in 10 CFR 50.12(a)(2)(ii) are present in that application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule.

Therefore, the Commission hereby grants a one-time exemption as described in section III above from the requirement in 10 CFR part 50, appendix J, III.D.2.(a) and III.D.3. to extend the allowed interval between the performance of Type B and C containment leak tests by 150 days.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will have no significant impact on the environment (59 FR 22870).

This exemption is effective upon issuance.

For The Nuclear Regulatory Commission,

Dated at Rockville, Maryland this 24th day of May 1994.

Jack W. Roe,

Director, Division of Reactor Projects—III/IV
Office of Nuclear Reactor Regulation.

[FR Doc. 94-13250 Filed 5-31-94; 8:45 am]

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