



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

SEP 17 2007

Michael Beaubien
Chief Operating Officer
St. John Macomb-Oakland Hospital
11800 E. Twelve Mile Road
Warren, MI 48093

Dear Mr. Beaubien:

This refers to the letter dated June 29, 2007, and to our telephone conversation on September 14, 2007. During the telephone conversation, we discussed voiding the request at this time to allow you time to gather additional information for the license amendment to change ownership/control for St. John Oakland Hospital. We will void your request without prejudice to resubmission. Please submit the additional information as requested in the enclosed memo.

When you resubmit your request please state that the resubmission is additional information to **Voided Controls No. 316348 and 316349.**

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions or require clarification on any of the information stated above, you may contact me at (630) 829-9839.

Sincerely,

A handwritten signature in cursive script that reads "William P. Reichhold".

William P. Reichhold
Materials Licensing Branch

Licenses No. 21-11494-01 and 21-01190-05
Dockets No. 030-02101 and 030-02005

Enclosed: Memo

Memo

FROM THE
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION 3
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

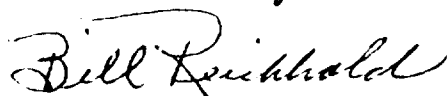
FAX (630) 515-1078

To: Michael Beaubien - Chief Operating Officer
Location: St. John Macomb-Oakland Hospital
Date: September 14, 2007
Subject: Information for Amendment Request

1. Please sign the amendment requests. We will return all unsigned amendment requests for proper signature. Representatives signing an amendment request must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Please see enclosed Item 13, "Certification" from NUREG-1556, Volume 15. NUREG-1556, Volume 15 may be found on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/>.
2. Please submit the information requested in Appendix F, "Information Needed for Transfer of Control" (enclosed) from NUREG-1556, Volume 15 for your amendment requests. Also please see Section 5, "Change of Control" (enclosed), from NUREG-1556, Volume 15.
3. Also, please submit documentation that the transferor and transferee agree to the change in ownership or control of licensed materials and activity (please have both parties sign this agreement) and the transferee is made aware of all open inspections items and its responsibility for possible resulting enforcement actions.

As we discussed by telephone on September 14, 2007, we will void your amendment requests at this time. You may resubmit your request as additional information to **Voided Controls No. 316348 and 316349**. We will resume our review upon receipt of your response. Please note, that a "void" is an administrative procedure that puts your amendment request "on hold" until you reactivate it by a written response. It costs you nothing, gives you time to prepare a quality response, and it regarded as a "good thing".

Please contact me at 630-829-9839 if you have any questions.

From the desk of

Bill Reichhold

June 29, 2007

United States Nuclear Regulatory Commission
Region III
2443 Warrensville Road
Suite 210
Lisle Illinois 60532-4352

030-02101 21-11494-01

Re: Notice of Merger of St. John Oakland Hospital
into St. John Health System-Detroit-Macomb Campus

030-02005 21-01190-05

Dear Registration Unit:

Effective July 1, 2007, St. John Oakland Hospital, located at 27351 Dequindre, Madison Heights, Michigan 48071, will be changing ownership. Its new owner will be St. John Health System-Detroit-Macomb Campus, with a provider number of 23-9005 and tax identification number of 38-3322109. This is an internal reorganization within St. John Health, and no change in St. John Oakland Hospital's clinical operation is planned at this time. St. John Oakland Hospital and St. John Health System-Detroit-Macomb Campus, doing business as St. John Macomb Hospital, located at 11800 East Twelve Mile, Warren, Michigan 48093, will be operated under common management and medical staff. Going forward, St. John Health-System-Detroit-Macomb Campus will conduct business under the new assumed names of St. John Macomb-Oakland Hospital, Macomb Campus, or Oakland Campus.

21-11494-01 OAKLAND CAMPUS C.A.C.-43

21-01190-05

If you have any questions, feel free to call me at (586) 573-5106, and please advise us if any further action on needs to be done on behalf of St. John Health System-Detroit-Macomb Campus.

Sincerely,

← NEED SIGNATURE

Joseph Tasse
President
St. John Health System-Detroit-Macomb Campus

316349

RECEIVED JUL 02 2007

11 07122007

CONTENTS OF AN APPLICATION

their existing radioactive waste management program. It is also helpful to indicate what components of the radioactive waste management program will remain unchanged.

Notes:

- NRC staff should refer to the applicable volume of NUREG-1556, or other appropriate guidance documents, for specific criteria to be used in reviewing licensee or applicant submissions.
- NUREG-1556 volumes and other guidance documents may be available electronically in the "Reference Library" at <<http://www.nrc.gov>>. For a paper copy of one of these documents, see the Notice of Availability (on the inside front cover of this report) or contact the appropriate NRC Headquarters or Regional Office.

10.12 ITEM 12: FEES

The next two items on NRC Form 313 are to be completed on the form itself. Enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

NRC does not impose fees for review of notification of change of control or of bankruptcy. However, a fee will be assessed if a license amendment or new license is required based on a review of the information provided.

10.13 ITEM 13: CERTIFICATION

In the case of applications for new or amended Part 30 or Part 40 licenses, individuals acting in a private capacity are required to date and sign the submitted NRC Form 313. Similarly, authorized representatives of the corporation or legal entity filing the application should date and sign the submitted NRC Form 313.

Applications for new or amended Part 70 licenses must be properly signed by the appropriate individuals.

Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. **NRC will return all unsigned applications for proper signature.**

Appendix F

Faxable Version of Information Needed for Transfer of Control Application

APPENDIX F

USNRC Region _____
Telephone: () - _____

Contact: _____
Fax: () - _____

Information Needed for Transfer of Control

Definitions:

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

5 CHANGE OF CONTROL

Regulations: 10 CFR 30.34(b); 10 CFR 31.2; 10 CFR 40.46; 10 CFR 70.36.

Criteria: The regulations require that "No license issued or granted pursuant to the regulations, nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing." Therefore, control of licenses cannot be transferred without the prior written consent of the Commission. These regulations apply to specific licensees, as well as certain general licensees.

This requires that licensees notify the Commission that they are undergoing a possible change of control. While this notification is not required within a certain time frame, NRC needs adequate time to review the response to ensure that the transfer is in accordance with the provisions of the Act. Once notified, NRC will ask that licensees submit the details of the transaction as described in Sections 5.1 through 5.6.

Definition of Control

In *Safety Light Corporation* (Bloomsburg Site Decommissioning), ALAB-931, 31 NRC 350 (1990), the Atomic Safety and Licensing Appeal Board stated, "[C]ontrol of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used." *Id.* at n. 46.

The Board went on to note, "In the instance of a corporate Part 30 or Part 50 licensee, that control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license." *Id.* at 367 (emphasis in original).

Control over licensed activities can be construed as the authority to decide when and how that license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control, depending on whether the authority over the license has transferred from one person to another. The transfer of stock or other assets is not necessarily a change of control. The central issue is whether the authority over the license has changed. Examples of transactions that would and would not constitute changes of control may be found in Appendix D.

NRC is not only concerned with change of control as it occurs in private business, but also as it affects Government agencies. For Government agencies, the lowest organizational level listed in Item 1 of the license is considered to be the licensee. Therefore, NRC should be informed whenever a change in ownership or control at the lowest organizational level listed on the license occurs.

CHANGE OF CONTROL

Some agencies possess a Master Materials License (MML), which authorizes a single organization within the agency to issue permits authorizing the use of licensed materials by individuals or organizations at multiple sites. NRC does not review or approve new MML permit holders and/or locations before use. A change in authority over a permit within the scope of a single master materials license would not constitute a change of control requiring the prior written consent of the Commission. However, a change in control from the MML licensee to another organization would require the Commission's prior written consent. For example, change of control over a medical center from one Government agency to another agency would require the Commission's prior written consent.

In the area of materials licensing, there are no categorical foreign ownership, control, or domination limitations. However, under Sections 57c, 63b, and 82b of the AEA, NRC must make a finding that issuance of the license for special nuclear material, source material, or byproduct material would not be "inimical to the common defense and security, and would not constitute unreasonable risk to the health and safety of the public." The Commission must make the same finding when consenting to a change of control. As a part of that determination, NRC will consider foreign ownership, control, and domination.

Although NRC has never adopted any explicit criteria for determining whether a particular transaction will be "inimical to the common defense and security," the Commission has historically focused on a relationship between a potential licensee and other entities involved in the transaction that could lead to the ultimate power of a foreign entity to direct the actions of the licensees with regard to licensed activities.

In the area of materials licenses, indirect control by a foreign entity of 100% of the licensee may be permissible, provided insulation measures are taken to protect the national security. Such measures include, but are not limited to, management directives shielding directors or board members from decisions involving classified or secret information, or from the management or control of special nuclear material. For example, one materials licensee merged with a foreign-owned corporation, ultimately becoming a wholly-owned subsidiary of that foreign entity. Based upon the licensee's commitments to maintaining its existing Headquarters, management, corporate structure, key personnel, and licensed activities, the staff found that the change of control of the licenses was not inimical to the common defense and security, did not present an unreasonable risk to the public health and safety, and was in accordance with the AEA.

In all cases, determining whether a change of control has taken place is the agency's responsibility. Whenever a change in ownership or control may occur, the licensee must so inform NRC.

Discussion: It is not the intent of NRC to interfere with the business decisions of licensees. NRC's focus is on the health and safety aspects, not on the financial intricacies, of the proposed transaction. NRC will require licensees to submit only such business information as is necessary to permit the Commission to determine whether a change of control will take place. NRC is required by law to ensure that the public's health and safety and the common defense and security

are not compromised and to be confident that when a licensee's program is undergoing a change of control, all efforts are made to ensure that the radiation safety aspects of the program are not degraded.

Response from the Licensee:

- Notification of a Change of Control with adequate time for NRC review;
- Information described in Sections 5.1 through 5.6.

5.1 DESCRIPTION OF TRANSACTION

Regulation: 10 CFR 30.34(b); 10 CFR 40.46; 10 CFR 70.36.

Criteria: Prior to approval of a change of control, NRC requires a complete, clear description of the transaction.

Discussion: The required description includes, but is not limited to, any transfer of stocks or assets, or mergers. This description will enable legal counsel to differentiate between name changes and changes of control, when necessary.

The licensee needs to include the new name of the licensed organization or state that there has been no name change. If appropriate, the licensee should include the new licensee contact and telephone number(s) to facilitate communications.

Response from the Licensee:

- Description of transaction;
- New name, if applicable;
- New licensee contact(s), including names and phone numbers.

5.2 CHANGES OF PERSONNEL

Regulation: 10 CFR 30.34(b); 10 CFR 40.46; 10 CFR 70.36.

Criteria: Prior to approval of a change of control, NRC requires that changes in personnel be documented, reviewed, and approved.

Discussion: Changes in personnel that need to be documented include individuals having control over licensed activities. This may include, in some cases, officers of a corporation or other management individuals who are listed on the license or referred to in the supporting documentation. This would also include any changes in personnel such as the Radiation Safety

CHANGE OF CONTROL

Officer, authorized users, or any other persons identified on the license or in the license application as having responsibility for radiation safety or authorized to use licensed material. Changes of personnel, as used in this report, does not include notifications regarding new authorized users made in accordance with 10 CFR 35.14.

As with any change in personnel listed on a license, pertinent information with regard to training, experience and qualifications applicable to the type of use will be required. The licensee should include applicable information concerning the qualifications, training, and responsibilities of any new individuals not previously listed on the current license or referred to in the supporting documentation. The specific information required will be found in the respective program-specific guidance for the type of operation in which a particular licensee is engaged, or it may be obtained by contacting the appropriate Headquarters or Regional license reviewer.

Response from the Licensee:

- Training and experience of *new* individuals to be listed on the NRC license.

Licensees or applicants should provide information about the training and experience of personnel relative to the licensed material requested in the application. Extraneous information, such as unrelated lists of publications, research grants, and committee and society memberships, should not be submitted. Licensees should also avoid providing personal information such as home addresses or telephone numbers, Social Security numbers, marital status, names of spouse and children, or age. Submittal of unrelated material serves only to slow the review process.

5.3 CHANGES OF LOCATION, EQUIPMENT & PROCEDURES

Regulation: 10 CFR 30.34(b); 10 CFR 40.46; 10 CFR 70.36.

Criteria: Prior to the approval of a change of control, the licensee needs to submit a complete description of any planned changes in location, facilities, equipment, or procedures.

Discussion: Provide a detailed description of any changes in the licensees' location(s) of use, facility description, equipment or procedures (i.e., changes in operating or emergency procedures) that would normally require a license amendment. Include any changes in organization that may not be identified in Section 5.2, Changes in Personnel.

The location must be described if the licensee is adding a place of use. A description of the contaminated condition of the facility, if any, is required if the licensee is removing a place of use. Refer to Section 5.6 for a more detailed description of the information needed. Any changes in the facilities where licensed material will be used or stored must be described. If equipment used in licensed activities is required to be described by license condition or regulation, or if

information regarding this equipment is requested by appropriate licensing guidance, a description of all equipment changes should be provided. Changes in procedures, including routine operating and emergency procedures, must be reviewed to ensure that they are adequate for the types and uses described on the license. Changes in personnel that would require a license amendment, even without the change of ownership, must be submitted as requested by appropriate licensing guidance.

Response from the Licensee:

- Describe changes in the organization that exercises control over the licensed program.
- Describe changes in place of use, including potentially affected adjacent areas, as required.
- Describe changes in facilities where licensed material is to be used or stored.
- Describe changes in equipment to be used in the licensed program.
- Submit relevant procedural changes.
- Describe changes in personnel, particularly those requiring a license amendment or notification regardless of the change of control.

Note: As previously stated, this guidance is not program-specific; therefore, any changes in the licensed program should be prepared and reviewed using the program-specific guidance, such as the NUREG-1556 series specific to the type of use or any other pertinent guidance published by NRC. Any questions should be directed to the Headquarters or Regional Office that routinely handles the licensing and/or inspection of the licensed program.

5.4 SURVEILLANCE RECORDS

Regulation: 10 CFR 30.34(b); 10 CFR 40.46; 10 CFR 70.36.

Criteria: Prior to the approval of a change of control, licensees or applicants must submit a review of the status of all applicable surveillance requirements and records. This should include an indication of whether the surveillance program is current and if it will be current at the time of transfer.

Discussion: Typical surveillance requirements include leak tests, physical inventories, ventilation measurements, and conductivity tests. Surveillance requirements specific to the types of use may be found in the license, the regulations, the appropriate NUREG-1556 or any other pertinent guidance published by NRC. The licensee must review any and all pertinent surveillance records to determine if they are current and ensure that they will be current at the time of transfer, or include an explanation if this is not to be the case. The licensee may perform the surveillance as authorized by its license. The licensee may also choose to have surveillance items performed by another party such as a contractor or the transferee, as authorized by the license, and if agreeable

CHANGE OF CONTROL

to both parties. It should be noted that the requirement for surveillance items in the regulations or the license is not waived due to a change of control.

Response from the Licensee:

- Submit a statement that all required surveillance has been performed, documented and reviewed, including the results, if appropriate.
- If surveillance items are not or will not be completed, the reasons, any corrective actions, and/or the date these corrective actions will be completed, should be submitted to NRC.

Note: As previously stated, this guidance is not program-specific; therefore, any changes in the licensed program should be prepared and reviewed using the program-specific guidance such as the NUREG-1556 series specific to the type of use or any other pertinent guidance published by NRC. Any questions should be directed to the Headquarters or Regional Office that routinely handles the licensing and/or inspection of the licensed program.

5.5 DECOMMISSIONING AND RELATED RECORDS TRANSFERS

Regulations: 10 CFR 30.34(b); 30.35(g); 10 CFR 40.46; 40.36(f); 10 CFR 70.36; and 70.25(g).

Criteria: Prior to the approval of a change of control, NRC regulations require that licensees arrange for the transfer and maintenance of records important to the safe and effective decommissioning of facilities involved in licensed activities. NRC also requires a description of the status of the licensed facility with regard to ambient radiation levels and fixed and/or removable contamination as a result of NRC licensed activities. The parties must confirm, in writing, that they accept full responsibility for the decommissioning of the site, including any contaminated facilities and equipment.

Discussion: Licensees are required to maintain certain records important to safe and effective decommissioning, including: evaluations concerning waste disposal by release as effluents (either air or water); release to sewers; incineration; disposal of liquid scintillation medium and animal tissue as if it were not radioactive; and disposal by methods specifically allowed through the license.

Subsequent to the transfer, the new licensee will become responsible for maintaining these records until the license is terminated. If licensed activities will continue at the same location, NRC requires confirmation that all the records of the aforementioned evaluations have been transferred to the new licensee. If the license will be terminated, these records must be forwarded to the appropriate NRC Regional Office.

No change of control or ownership or license termination will be authorized until all required records have been transferred to the new licensee or to NRC, as appropriate.

These regulations require that before licenses are transferred or assigned, all records be transferred to the new licensee. The regulations require that all records of measurements and calculations used to evaluate the release of radioactive effluents to the environment and records of certain disposals be transferred to the new licensee prior to the license being transferred or assigned, unless the existing licensee was only authorized to possess and use unsealed material with a half life of less than 65 days or material in a sealed source form.

The current licensee must document ambient radiation levels and the presence or absence of contamination. The documentation must include, as appropriate, the method and sensitivity of the evaluation. If contamination is present, the documentation should describe how and when decontamination will occur or indicate that the timing and means of decontamination and/or decommissioning have not yet been determined.

The current licensee must also discuss how the parties agree to assume responsibility for the decontamination and decommissioning of licensed facilities. Those licensees required under 10 CFR 30.35, 40.36, and/or 70.25 to provide evidence of adequate resources to fund any required decommissioning must describe the effect that the change of control will have on financial assurance for decommissioning. As necessary, documents describing financial assurance must be amended to reflect the change in control. This documentation may refer to decontamination plans, including any required financial assurance arrangements of the transferor, that were previously submitted in support of a decommissioning funding plan.

Response from the Licensee:

- Describe the method and proposed timetable for the transfer of required records.
- Provide a commitment by the transferee to maintain the records received from the transferor.
- Provide a description of the facility with regard to contamination and ambient radiation levels.
- Describe any decontamination to prepare the facility for decommissioning prior to the change of control.
- If decommissioning will not occur until after the change of control, describe any contamination and confirm that the transferee is knowledgeable of the extent and levels of contamination and applicable decommissioning requirements.

Note: Licensees authorized to possess and use only licensed material with a half-life of less than 65 days and/or only licensed material in sealed form are excepted from this requirement to maintain and transfer effluent and disposal records. **All** licensees are required to maintain and transfer only those records for unsealed materials with a half-life greater than 65 days.

CHANGE OF CONTROL

Notes:

- Licensees should contact NRC Regional or Headquarters personnel to determine acceptable methods and criteria for decommissioning and releasing licensed facilities for unrestricted use.
- The licensee or applicant should refer to Section 10.11 for a discussion of the records involved in the management and disposal of radioactive waste specific to their type of licensed program.

5.6 TRANSFEREE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

Regulation: 10 CFR 30.34(b); 10 CFR 40.46; 10 CFR 70.36.

Criteria: The new licensee (transferee) must either: (1) submit a commitment to abide by all constraints, license conditions, requirements, representations, and commitments identified in and attributed to the existing license; or (2) provide a description of its own program to comply with the license and all applicable regulations.

Discussion: The transferee may agree to abide by all constraints, conditions, requirements, representations, and commitments previously made to NRC by the transferor. This would include, but not be limited to, information submitted in support of license amendments (including documents itemized in the tie-down condition of the license) and the maintenance of decommissioning records required by 10 CFR 30.35. Alternatively, the transferee may submit a description of its own program to ensure compliance with the license and regulations.

This would also include completion of corrective actions for open inspection items and enforcement actions and, if required, implementation of site decontamination and decommissioning activities.

With regard to open inspection items and/or enforcement actions, the transferee should confirm, in writing, that it is knowledgeable of and accepts full responsibility for open inspection items and/or any resulting enforcement actions. Alternatively, the transferee may propose other measures for meeting these requirements, or the transferor may provide a commitment to close out all such actions with NRC before license transfer.

Information Required of the Licensee:

- An agreement to abide by all constraints, license conditions, requirements, representations, and commitments identified in and attributed to the existing license (or) a description of the transferees' program to ensure compliance with the license and regulations;
- A description of action to be taken to resolve open inspection and enforcement issues.