
MINNESOTA DEPARTMENT OF HEALTH



GUIDANCE CONCERNING CHANGES OF CONTROL INVOLVING RADIOACTIVE MATERIALS PROGRAMS

The logo for the Radioactive Materials Unit (RAM) of the Minnesota Department of Health. It features a circular border with the text "Radioactive Materials Unit - Minnesota Department of Health" and a central illustration of a ram's head with the letters "RAM" below it.	<p>Radioactive Materials Unit Minnesota Department of Health 625 Robert Street North P.O. Box 64975 St. Paul, Minnesota 55164-0975 (651) 201-4545</p>
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Guidance Concerning Changes of Control Involving Radioactive Materials Programs

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Management Responsibility

The Minnesota Department of Health (MDH) recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. MDH believes that consistent compliance with its rules provides reasonable assurance that licensed activities will be conducted safely. MDH also believes that effective management will result in increased safety and compliance. "Management" refers to the processes for conducting and controlling the radiation safety program and to the individuals who are responsible for those processes and who have authority to provide necessary resources to achieve regulatory compliance.

It is not the intent of MDH to interfere with the business decisions of licensees. MDH's focus is on the health and safety aspects, not on the financial intricacies, of the proposed transaction. MDH will require licensees to submit only such business information as is necessary to permit the commissioner to determine whether a change of control will take place. MDH is required by statute to ensure that public health and safety is 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 performance of the radiation safety aspects of the program is not degraded.

It is the licensee's obligation to keep the license current. Should a change of control result in a change to the licensee's program, the licensee should amend the license to reflect that change. If any of the information provided in the original application is to be modified or changed, the licensee should submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee should submit an application for a license renewal at least 30 days before the expiration date.

Persons applying for an initial license should update and modify their pending applications if they are undergoing a change of control. Generally, licensee or applicant management has a responsibility for all aspects of the radiation safety program including, but not limited to, the following:

- Radiation safety, security and control of radioactive materials, and compliance with rules;
- Completeness and accuracy of the radiation safety records and all information provided to MDH;
- Knowledge about the contents of the license and application;
- Meticulous compliance with current MDH rules and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and that meticulous compliance with rules is maintained;
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities;
- Prohibition against discrimination of employees engaged in protected activities;
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions;
- Obtaining MDH's prior written consent before changing control of the license;

As discussed above, licensee's management has specific responsibilities with regard to changes of control. Control of licensed activities cannot be changed without prior written consent from MDH. Licensees are expected to notify MDH of a proposed change of control in a timely manner, allowing MDH enough time to carry out its statutory mandate of ensuring that licensed materials are adequately safeguarded and that public health and safety is protected.

Licensee management is strongly cautioned that cases where change of control, such as change of ownership, occur without MDH's prior written consent will be considered to be violations of MDH rules. Failure to receive the required MDH approval prior to a change of control of licensed activities may be considered to be a Severity Level III violation warranting escalated enforcement

action. Escalated enforcement action may include the issuance of orders, the imposition of monetary civil penalties, or the modification, suspension, or revocation of the license against one or both of the parties involved.

MDH recognizes that information regarding a proposed change of control may be extremely sensitive and that the public release of such information may have an adverse impact on the licensee, as well as other persons potentially involved in the change of control. Licensees, or other persons wishing to protect sensitive information regarding proposed changes of control, should request that sensitive information be protected

Definition of "Control"

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.

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

Changes of ownership or control resulting from legal changes such as mergers, buy-outs, or majority stock transfers require prior consent. In some cases, internal management adjustments and actual changes of control may be difficult to distinguish. Therefore, it is imperative that licensees notify the commissioner of not only actual, but also suspected changes of control so that the agency may make a determination. In general, no MDH license for materials may be transferred, assigned, or disposed of unless MDH gives its prior consent in writing.

In cases where a transferee proposes to purchase a licensed operation, and the transferor continues in business as a separate entity without the license, the transferee should submit notification to the commissioner that reflects both the change in identity of the licensee and any other pertinent changes in the operation. The transferee can always apply for a new license by providing a complete application, for which it may use the transferor's docketed documents as a basis. The transferor is also obligated to notify MDH of the proposed change of control; furthermore, if MDH issues a new license, the transferor should request termination of its license in a separate proceeding.

Description of Transaction

The required description includes, but is not limited to, any transfer of stocks or assets, or mergers. This description will enable MDH 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. See Attachment I for a complete list of information that should be provided.

Changes of Personnel

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 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, do not include notifications regarding new authorized users.

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 MDH

Changes of Location, Equipment and/or Procedures

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 "Changes in Personnel."

The location should 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. Any changes in the facilities where licensed material will be used or stored should 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 should 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, should be submitted as requested by appropriate licensing guidance¹.

Surveillance Records

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 rules, the appropriate regulatory guide published by MDH. The licensee should 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 to both parties. It should be noted that the requirement for surveillance items in the rules or the license is not waived due to a change of control.

Decommissioning and Related Records Transfers

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.

¹ 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 published by Minnesota Department of Health specific to the type of use.

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, MDH 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 should be forwarded to MDH.

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 MDH, as appropriate.

These rules require that before licenses are transferred or assigned, all records be transferred to the new licensee. The rules 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 should document ambient radiation levels and the presence or absence of contamination. The documentation should include, as appropriate, the method and sensitivity of the evaluation. If contamination is present, the documentation should describe how and when decontamination would occur or indicate that the timing and means of decontamination and/or decommissioning have not yet been determined.

The current licensee should also discuss how the parties agree to assume responsibility for the decontamination and decommissioning of licensed facilities. Those licensees required to provide evidence of adequate resources to fund any required decommissioning should describe the effect that the change of control will have on financial assurance for decommissioning. As necessary, documents describing financial assurance should 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.

Transferee's Commitment to Abide by the Transferor's Commitments

The transferee may agree to abide by all constraints, conditions, requirements, representations, and commitments previously made to MDH 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. Alternatively, the transferee may submit a description of its own program to ensure compliance with the license and rules. 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 MDH before license transfer.

ATTACHMENT I

INFORMATION NEEDED FOR CHANGE OF CONTROL

Licensees should provide full information and obtain MDH's prior written consent before transferring control of the license. Using the following checklist, provide the information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). Submit information concerning the change of control and a completed copy of this checklist to MDH.

MDH Notification Only

- Yes No Is there a new name of the licensed organization?
- Yes No Is there a new licensee contact and telephone number(s) to facilitate communications?

License Amendment Required

- Yes No Are there any changes in personnel having direct control over licensed activities or any changes in personnel named in the license such as Radiation Safety Officer, Authorized Users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material?
- The licensee should provide a complete description of any planned changes in organization and should include information concerning the qualifications, training, and responsibilities of new individuals.
- Yes No Are there any changes in organization, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control?
- Yes No Are there changes in the facility location?
- Yes No Are there any changes in the use, possession, or storage of the licensed materials?

Additional Questions Regarding Transfer of Control

- Yes No Will all quality control activities and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) be current at the time of transfer?
- If yes, provide a description of the status of all quality control activities and records.
- Yes No Will all records concerning the safe and effective decommissioning of the facility; public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, be transferred to the new licensee, if licensed activities will continue at the same location, or to the MDH for license terminations?

Yes No Is contamination is present?

Provide a description of the status of the facility. Specifically, the presence or absence of contamination should be documented.

Yes No N/A Will decontamination occur before transfer? If not, the new owner should agree to assume full liability for the decontamination of the facility or site.

Documentation and Commitments for Transfer of Ownership

Provide a complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.

Provide information about how the current owner proposes to divide the assets and responsibility for any cleanup needed at the time of transfer. Include a description of any decontamination plans and financial assurance arrangements of the new owner.

Confirm that the new owner agrees to abide by all commitments and representations previously made to MDH. These include, but are not limited to maintaining decommissioning records, implementing decontamination activities and decommissioning of the site, and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the current owner should provide a commitment to decontaminate the facility before transferring control.

OR

The new owner should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning.

With regard to open inspection items, etc., the current owner should provide a commitment to close out all such actions with MDH before license transfer.

OR

The new owner should confirm, in writing, that it is aware of all open inspection items; it will assume responsibility for possible resulting enforcement actions; and it accepts full responsibility for open inspection items and any resulting enforcement actions. The new owner can propose alternative measures for meeting the requirements.

Provide a commitment by the new owner to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license.

OR

The new owner should provide a description of its program to ensure compliance with the license and regulations.