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<u>Policy Concern:</u> This policy concerns action to be taken if patients, who, according to regulations should be hospitalized, decide to discharge themselves.

<u>Policy Implementation:</u> The Radiation Safety Officer is directed to implement this policy upon approval by the Radiation Safety Committee. All necessary procedure changes and instructions to implement this policy must be approved by the Radiation Safety Officer.

<u>Discussion:</u> Under 10 CFR 35.75/OAC 3701:1-58-30 certain patients receiving radiopharmaceutical therapy and/or brachytherapy require hospitalization. When questioned, the Nuclear Regulatory Commission states they understand that a licensee cannot force a patient to remain in the hospital; however, the licensee should take reasonable efforts to hospitalize patients required to be hospitalized under 10 CFR 35.75.

This policy statement was developed because in 1998 two radiopharmaceutical therapy patients requiring hospitalization under 10 CFR 35.75 indicated they would be discharging themselves. Discussions with the patients resulted in the patients remaining hospitalized. One of the physicians involved requested that a policy be drafted so he can ensure he is taking steps expected by the University of Cincinnati to ensure compliance with the regulations.

The issue was discussed with UC Risk Management. UC Risk Management felt the issue was similar to patients who discharge themselves against medical advice; therefore this policy was drafted using University Hospital Policy II-405 "Patients Who Insist on Discharge at Serious Risk to Themselves (Medical Hold)" as a guide. The major differences between the two policies is that University Hospital Policy II-405 was drafted with the primary concern being the risk the patient creates for themselves because of self-discharge and this policy is drafted with the primary concern being the risk the patient may cause to others.

Revision 1: In 1998, the state of Ohio obtained agreement state status, with the Ohio Department of Health (ODH) the regulatory agency. In 2005, the ODH enacted regulations/rules specific for the medical use of radioactive material. The rules are listed in Ohio Administrative Code (OAC) chapter 3701:1-58 and are equivalent to the NRC regulations. In 2006, University Hospital separated from the University of Cincinnati. It was at the University Hospital that most permanent implants were performed. In 2012, the Radiation Safety Officer noted this policy had not been updated to reflect the changes and submitted a revision for RSC review and approval. Prior to drafting changes to this policy, the RSO discussed the issues and possible changes with CCHMC Protective Services.

Policy Statement:

When a patient who is hospitalized under OAC 3701:1-58-30 indicates a desire to leave the hospital reasonable efforts should be made to prevent the patient from leaving the hospital until the following are accomplished:

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Radiopharmaceutical Therapy

- 1. Contact the patient's treating physician who will determine whether the patient has the capacity to give informed consent. Capacity to consent means the ability to understand the condition being treated and the risks they could cause to other persons. Psychiatric or other consultation should be requested as necessary to aid in the determination; however, the determination of the capacity remains the decision of the responsible physician. (Note: if the patient is a minor this determination shall be made of the individual who is responsible, e.g., parent or guardian, of the patient.)
- 2. Clarify the reasons for the patient's desire to leave. If possible, provide corrective action.
- 3. Provide the patient or, in the case of a minor, the responsible individual, an explanation of the risks involved. This may include explanations by the treating physician, Nuclear Medicine personnel, and/or Radiation Safety personnel.
- 4. If appropriate, the patient's family/significant others should be contacted to assist in clarifying the patient's wishes and providing alternatives to discharge.
- 5. If everything fails and the patient continues to indicate he/she will discharge himself/herself before authorized under OAC 3701:1-58-30 (i.e., released by Radiation Safety) the following action should be taken:
 - a. If not currently present, contact Radiation Safety and the treating physician immediately. Advise them of the situation. If at all possible get the patient to remain until Radiation Safety arrives.
 - b. Attempt to determine radiation levels at 1 meter before the patient leaves. The radiation level measurements should be taken as close as possible to the time of self-discharge. Contacting Radiation Safety early in the process so they are present at time of self-discharge will help to ensure radiation level measurements are taken as needed.
 - c. Record action taken, and the date and time of discharge into the patient's hospital record.
 - d. Provide a copy of the portion of the hospital record with self-discharge information to the Radiation Safety Office (M.L. 0591) and the Nuclear Medicine physician.
 - e. Radiation Safety shall prepare a Radiation Safety incident report for Radiation Safety records. A copy of the report shall be provided to Risk Management.
- 6. Any additional requirements under the hospital's policy for discharge against medical advice shall also be followed.

Temporary Brachytherapy

1. Contact the patient's treating physician who will determine whether the patient has the capacity to give informed consent. Capacity to consent means the ability to understand the condition being treated and the risks they could cause to other persons. Psychiatric or other consultation should be requested as necessary to aid in the determination; however, the

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determination of the capacity remains the decision of the responsible physician. (Note: if the patient is a minor this determination shall be made of the individual who is responsible, e.g., parent or guardian, of the patient.)

- 2. Clarify the reasons for the patient's desire to leave. If possible provide corrective action.
- 3. Provide the patient or, in the case of a minor the responsible individual, an explanation of the risks involved. This may include explanations by treating physician, Radiation Oncology personnel, and/or Radiation Safety personnel.
- 4. If appropriate, the patient's family/significant others should be contacted to assist in clarifying the patient's wishes and providing alternatives to discharge.
- 5. If everything fails and the patient continues to indicate they will discharge himself/herself before authorized under OAC 3701:1-58-30 (i.e., released by Radiation Safety):
 - a. If not currently present, contact Radiation Oncology and Radiation Safety immediately. Advise them of the situation.
 - b. The patient shall be detained as necessary to ensure the sources are removed prior to departure. CCHMC Protective Services may be contacted to prevent patient departure with temporary implant, because the sources are hospital and/or University property. CCHMC Protective Service may request assistance from UCPD. The responsible physician (i.e., treating physician or on-call Radiation Oncologist) or nurse may order patient restraint for patient and/or staff safety. Restraint is a last resort and the staff should document restraint was used for source removal and to prevent an unacceptable risk to themselves, staff and the public. When restraint proves to be necessary to prevent departure, CCHMC Patient Relations must be notified. UC Risk Management and CCHMC Legal should also be consulted and the incident should be fully documented in the patient's chart by the responsible staff.
 - c. The individual responding from Radiation Oncology should complete the following:
 - i. Remove the radiation sources and record action taken and date and time of source removal into the patient's hospital record and on the written directive.
 - ii. Record on the written directive that the patient demanded the treatment be terminated against medical advice.
 - iii. If Radiation Safety is not present, perform a survey of the patient to ensure all sources were removed. If Radiation Safety is present, Radiation Safety will perform this survey.
 - iv. Provide Radiation Safety with a copy of the written directive, with the notation about patient termination of the procedure.
 - d. Radiation Safety shall prepare a Radiation Safety incident report for Radiation Safety records. A copy of the report shall be provided to UC Risk Management and CCHMC Legal.

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Permanent Brachytherapy

- 1. Contact the patient's treating physician who will determine whether the patient has the capacity to give informed consent. Capacity to consent means the ability to understand the condition being treated and the risks they could cause to other persons. Psychiatric or other consultation should be requested as necessary to aid in the determination; however, the determination of the capacity remains the decision of the responsible physician. (Note: if the patient is a minor this determination shall be made of the individual who is responsible, e.g., parent or guardian, of the patient.)
- 2. Clarify the reasons for the patient's desire to leave. If possible provide corrective action.
- 3. Provide the patient or, in the case of a minor the responsible individual, an explanation of the risks involved. This may include explanations by treating physician, Radiation Oncology personnel, and/or Radiation Safety personnel.
- 4. If appropriate, the patient's family/significant others should be contacted to assist in clarifying the patient's wishes and providing alternatives to discharge.
- 5. If everything fails and the patient discharges himself/herself before authorized under OAC 3701:1-58-30 (i.e., released by Radiation Safety):
 - a. Contact Radiation Safety and the Radiation Oncology physician.
 - b. Record action taken, and date and time of discharge into the patient's hospital record.
 - c. Provide a copy of the portion of the hospital record with discharge information to the Radiation Safety Office (M.L. 0591) and the Radiation Oncology physician.
 - d. Radiation Safety shall prepare a Radiation Safety incident report for Radiation Safety records. A copy of the report shall be provided to Risk Management.
- 7. Any additional requirements under the hospital's policy for discharge against medical advice shall also be followed.

<u>Policy Approval:</u> Original approval September 15, 1998. Revision 1 approved November 14, 2012