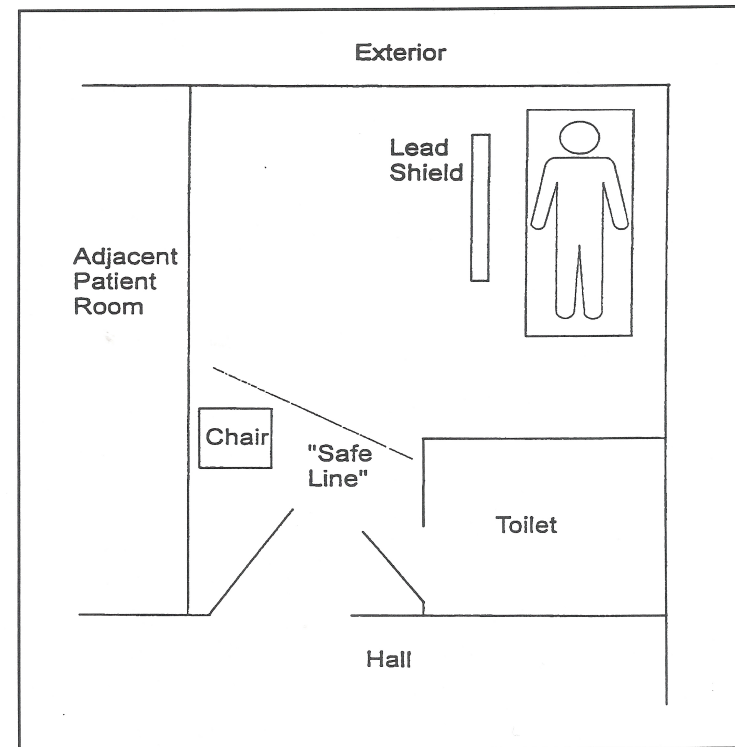


Radiation Safety Concerns in Brachytherapy

The sources used for brachytherapy treatments require special safety considerations, because they are always "on".

Room Diagram





Brachytherapy sources require storage in a heavily shielded "safe or safe area" which is secure from theft or loss. A careful inventory must be maintained of all sources, and any time a source is removed or returned, a log entry must be made and a complete inventory performed.



A facility must develop and implement procedures to ensure that exposure rates from therapy treatments are limited to minimize doses to the patients, occupational workers, and members of the public.



Every Brachytherapy treatment (implant) requires a complete written directive. Before the treatment is administered a certification must be made that the implant was assembled in accordance with the directive



POLICIES &
PROCEDURES
MANUAL

10 CFR 35.41 requires facilities to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users in accordance with the written directives.



POLICIES &
PROCEDURES
MANUAL

Radiation Safety policies and procedures should include all operational protocols and incorporate the regulatory requirements. Emergency procedures should be developed addressing all types of licensed material and devices used and should be posted in restricted areas where sealed sources are used or stored.



Emergency instructions must include the names and telephone numbers of persons to be notified, particularly the Radiation Safety Officer, staff, state and local authorities, and the NRC, when applicable.



Additionally, the instructions must contain procedures on evacuation and security of the involved area(s), source recovery, area reentry, and decontamination of facilities (if applicable).



All equipment necessary for complying with emergency procedures shall be immediately accessible in the treatment room or console area and may include remote handling tools, allen keys, and shielded containers.



Practice drills, using non-radioactive (dummy) sources (when possible), including dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for patient removal must be practiced annually.



POLICIES &
PROCEDURES
MANUAL

No safety device is effective if it is not working, so frequent testing is needed. Quality assurance and quality control programs will incorporate the regular equipment testing, the audits, and equipment maintenance required to provide the safe environment for all individuals who may be exposed.

Leakage Testing

According to 35.67 there are multiple requirements for facilities for safety and handling requirements. The brachytherapy sources must be tested for leakage before the first use unless there is a certificate from the supplier indicating that the source was tested within the 6 months or other intervals approved by the commission of an agreement state in the Sealed Source and Device Registry before transfer to the facility.

Leakage Testing

The sources must be tested for leakage on intervals not to exceed 6 months. The leak test must be able to detect the presence of 185 Bq (0.005 μ Ci) of radioactive material in the sample and if this level is exceeded, the source must be immediately withdrawn from service

Leakage Testing

If a source is found to be leaking, 35.3067 requires that a report must be filed in 5 days. Sources exempt from leak testing:

- if the half life is less than 30 days
- if the sources is a gas
- seeds of Ir -192 encased in a nylon ribbon
- beta or gamma-emitting sources with 03.7 MBq (100 μ Ci) or less of material
- alpha-emitting sources with .3 7 MBq (10 μ Ci) or less of material

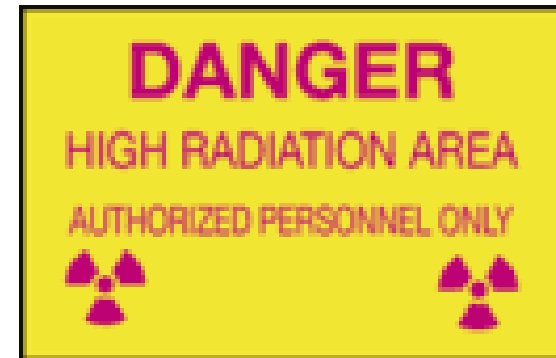
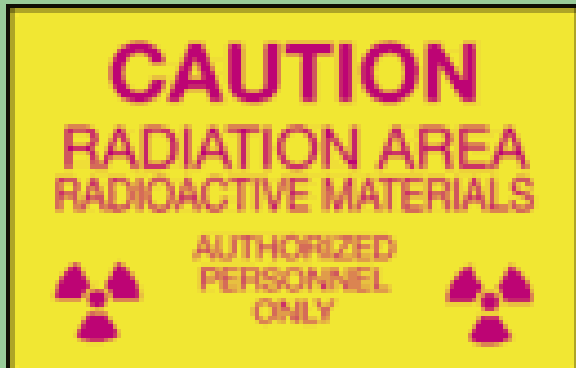
Leakage Testing



Sources in storage and not being used do not have to be tested until put back in service or transferred. A physical inventory must be performed semi-annually for all sources except those in the gamma knife. An inventory record must be maintained in accordance with 35.2067 (b).

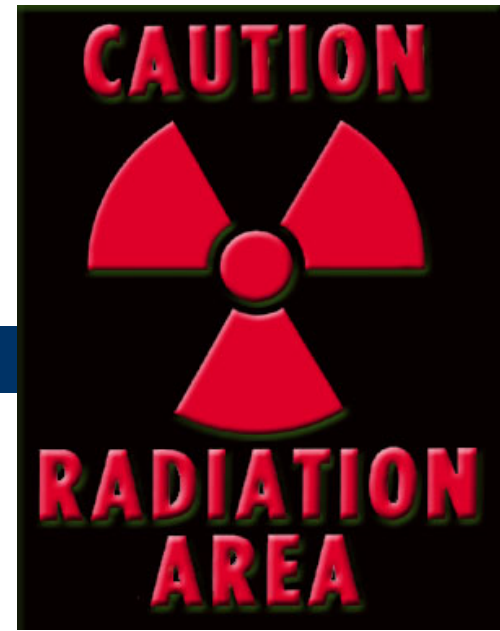
Postings and Signage

There are a number of postings that are necessary during a brachytherapy treatment. These include not only the traditional "Caution" signs but also signs that provide information regarding radiation levels and time spent in various areas within the patient's room.



The caution signs used in any brachytherapy program are three in number:

- Caution Radioactive Materials,
- Caution - Radiation Area,
- Caution - High Radiation Area.



20.1003 defines a Radiation Area as any area where a major portion of the body could receive a dose equivalent greater than 5.0 mrem in any one hour at a distance of 30 cm to an individual.



A High Radiation Area is defined as any area where a major portion of the body could receive a dose equivalent in excess of 100 mrem in any one hour at 30 cm from the source.



A very High Radiation Area is defined as an area in which an individual could receive an absorbed dose in excess of 500 rads in one hour at one meter from the source.



The sign Caution - Radioactive Materials has been used traditionally in an area where a major portion of the body would receive between 0.6 to 5.0 mrems in any one hour. By actual definition, according to 20.1902(e), the Caution - Radioactive Material sign is needed for rooms where used or stored quantities exceed 10 x quantities in Appendix C. (e.g. Ir-192 = 10 μ Ci, Cs-137 = 100 μ Ci, I-131 = 10 μ Ci, Tc-99m = 10 mCi).



The radiation signs warn that the patient within this room is undergoing radioactive treatment and that special rules must now apply for visitors, nurses and attendants. In addition to the Caution - Radioactive Materials sign on a patient room door, a note should be posted on the door indicating how long (and where) visitors may stay in the room. A sign may also be placed at the foot of the bed.



A good radiation safety program would also suggest that the Caution - Radioactive Materials signs be placed ON the patient's chart as well as IN the patient's chart. doing, This will warn the attending physicians and nursing personnel who would pick up the patient's chart that they are dealing with a person undergoing radioactive therapy treatment



When transporting the radioactive materials from storage site to insertion site and back the transport cart should also be properly labeled. Identibands are also available to place on the patient who is undergoing radioactive therapy.



There are some exceptions to posting as described in 20.1903:

1. Area or rooms containing radioactive materials for < 8 hours if constantly attended by trained individual and area/room is subject to licensee's control.
2. Rooms/area with patient released from confinement according to 35.75.
3. Sealed source releasing <5 mR/hr at 30 cm.
4. Rooms where patients containing byproduct material are constantly attended by knowledgeable personnel.



Use of Sources for Brachytherapy

1. Cs-137 and Co-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.
2. Au-198, I-125 and Pd-103 as a sealed source in seeds for interstitial treatment of cancer.
3. Sr-90 as a sealed source in an applicator for treatment of superficial eye conditions.
4. Ir-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.



Generally, these devices are handled manually by the licensed user and are placed in the appropriate applicator devices to ensure that the proper radiation dose is provided to the specific areas of treatment desired by the Radiation Oncologist.

SAFETY INSTRUCTION

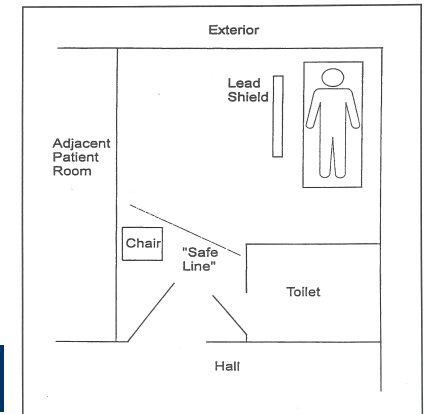


It is extremely important that safety instructions are given to the patient, to the visitors, and to nurses during the time that any radioactive sources are implanted into the therapy patient. The general requirements of such safety instructions are that they must be sufficient and easily understood so the licensed user has control over the patient, and control over the visitor, with special emphasis on contamination and waste control as well. It should be understood by all that the Radiation Safety Officer must be notified in the case of a medical emergency or death.



SAFETY INSTRUCTION

Room Diagram

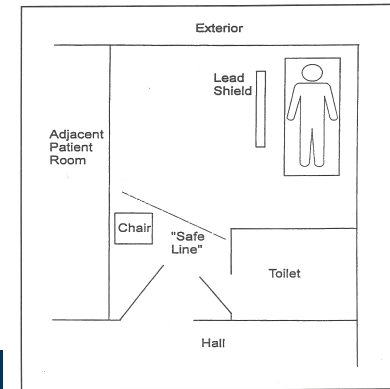


The choice of an appropriate room is most important to be sure that radiation levels are not exceeded in the environs of the therapy room. An appropriate room would be one in a corner of the building at the end of the hall, which would allow the therapy treatment room to have one or two outside walls, with perhaps the end of a corridor or a stairwell on the third wall, leaving only one wall to be concerned about for radiation controls. The patient's bed should be moved as far as possible into the corner formed by the two exterior walls to take advantage of the inverse square law as a radiation protective measure



If the hospital has a radiation shield, this shield should be rolled in a position so the shield will protect the nursing staff that would be called to attend the patient, as well as shielding the patient in the adjacent room from the radioactive materials.

Room Diagram



A good way to limit exposure to visitors is to determine a radiation safety line behind which the exposure levels are 2 mR/hr or less, and label the floor in the patient's room with yellow radioactive tape. If one places a visitor's chair behind this line, then the limits recommended in 20.1301 will not be exceeded. 20.1301 dictates that the TEDE to members of the general public does not exceed 100 mrem (mSv) in a year and the dose in an unrestricted area not exceed 2 mrem (0.02 mSv) in any one hour.



PDM-101
High Sensitivity Type



The NRC defines controlled area as an area outside of a restricted area access to which can be limited by the licensee for any reason. Therefore, a member of the general public may enter the restricted area of the therapy patient's room but can assume the radiation risks and limits of an occupational person. If such a less restrictive program was allowed, then the RSO would have to determine if the exposures exceeded 10% of 20.1201. If they did, then it would be the responsibility of the RSO to (1) issue a personnel monitor, and (2) provide radiation safety instruction as done to all other occupationally exposed individuals.



The patient should also be instructed in simple principles of radiation protection, especially visitors allowed to enter the room. Usually the brachytherapy patient is lucid, and can understand the goals of the Radiation Safety Officer. The instructions should surely indicate to the patient that he/she remain in the room and in bed at all times. The determination of the 2mR/hr line should be explained to the patient so that the patient can in turn control the radiation exposures to visitors if they are allowed.



The patient should also understand that the practice of allowing visitors younger than 18 is to be discouraged. If such a visit is absolutely necessary, it must be reviewed on a case by case basis with the Radiation Safety Officer.

Should the visitor be allowed to enter the therapy patient's room, it must be made clear to him/her how long he/she can stay inside the room, and the place that he/she must stay in order to satisfy the radiation safety regulations.



The most important group of persons involved in the brachytherapy treatment is the nursing staff.



The instructions given to nurses must be repeated time and time again from the first day of orientation to at least one time per year. Records should be kept of such nursing instruction. It is important that nurses understand and are aware of what the brachytherapy treatment is designed to do and to have an idea of what the sources look like.



It often falls upon the nurses to be actively involved in the problems of patient control. The nurse is most likely to note that the patient does not stay in the bed in the presence of visitors. Most likely the nurse would be summoned in the event that the source becomes dislodged. It is also the nurse who would be involved in the visitation rights of the patient as well as where visitors can sit within the patient's room. The nurses must always be aware of the caution signs and the meanings of those caution signs so that they can better control their own personal radiation exposures, as well as exposure to others who visit the patient's room.



Insist that nurses be monitored through personnel monitoring devices to ensure that proper levels have been maintained. The nursing staff must also be aware of the limitations for visitors regarding pregnancy. Under no circumstances, is the visit by a pregnant woman allowed in the therapy patient's room. The nursing staff must constantly be apprised of the procedures that require notification of the RSO such as in cases of an emergency or the patient's death.



It is rare that a wire or applicator cell (Cs-137 and Co-60) becomes a radiation hazard because these are usually placed in the patient and are well packed to ensure they do not fall out. That is not to say that an incident has not happened.




Emergency response equipment must be available near each treatment room to respond to a source that has become dislodged from the patient or lodged within the patient following removal of the source applicators



In order to properly carry out a radiation safety practice when brachytherapy patients are involved, the RSO must possess both a radiation detection survey meter as well as a radiation measurement survey meter. It is also important that the Radiation Safety Officer and/or licensed users know how to operate these survey meters, so the appropriate survey meter is used at the proper time.



35.404 requires that each patient be surveyed following the implantation and removal of sources that all sources are located and accounted for and that a record of these surveys be maintained.. Sources must be returned to storage as soon as possible after removal from the patient and there shall be accountability for the location of the sources in use and in storage at all times, 35.406. A record of source accountability is required by 35.2406.



In January 2004, the International Atomic Energy Agency published the document *Code of Conduct on the Safety and Security of Radioactive Sources*.

Code of Conduct on the Safety and Security of Radioactive Sources

- Medical
- Industrial
- Commercial

Annex 1: list of sources covered by the code category 1

Sources, if not safely managed or securely protected would be likely to cause permanent injury to a person who handled them or were otherwise in contact with them for a few minutes.



Annex 1: list of sources covered by the code category 2

Sources, if not safely managed or securely protected could cause permanent injury to a person who handled them or was in contact for a few minutes.

minutes



Annex 1: list of sources covered by the code category 3

Sources if not safely managed or securely protected, could cause permanent injury to a person who handled them for some hours.

Hours



ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES

Radionuclide	Category 1 1000 X D (TBq) (Ci)s	Category 2 10 X D (TBq) (Ci)s	Category 3 D (TBq) (Ci)s
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Am-241	6.E+01	2.E+03	6.E+01	2.E+01	6.E-02	2.E+00
Am-241/Be	6.E+01	2.E+03	6.E+01	2.E+01	6.E-02	2.E+00
Cf-252	2.E+01	5E+02	2.E+01	5.E-00	5E+02	5.E-01
Cm-244	5.E+01	5.E-01	5.E-01	1.E+01	5E+02	1.E+01
Co-60	3.E+01	8.E+02	3.E-01	8.E+00	3.E-02	8E-01
Cs-137	1.E+02	3.E+04	1.E+01	3.E+01	8.E-02	2.E+00
Gd-153	1.E+03	3.E+04	1.E+01	3.E+02	8.E-01	3.E+01

ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES

Radionuclide	Category 1 1000 X D (TBq) (Ci)s	Category 2 10 X D (TBq) (Ci)s	Category 3 D (TBq) (Ci)s
--------------	---------------------------------------	-------------------------------------	--------------------------------

Ir-192	8.E+01	2.E+03	8.E-01	2.E+01	8.E-02	2.E+00
Pm-147	4.E_04	1.E+06	4.E+02	1.E+04	4.E+01	1.E+03
Pu-238	6.E+01	2.E+03	6.E+01	2.E+01	6.E-02	2.E+00
Pu-239 _b /Be	6.E+01	2.E+03	6.E+01	2.E+01	6.E-02	2.E+00
Ra - 226	4.E+01	1.E+03	4.E-01	1.E+01	4.E-02	1.E+00
Se-75	2.E+02	5.E+03	2.E+00	5.E+01	2.E-01	5.E+00
Sr-90(Y-90)	1.E+03	3.E+04	1.E+01	3.E+02	1.E+00	3.E+01

ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES

Radionuclide	Category 1 1000 X D (TBq) (Ci)s	Category 2 10 X D (TBq) (Ci)s	Category 3 D (TBq) (Ci)s
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Tm-170	2.E+04	5.E+05	2.E+02	5.3+03	2.E+01	5E+02
Yb-169	3.E+02	8.E+03	3.E+00	8.E+01	3.E-01	8.E+00
Au-198*	2E+02	2.E+03	2.E+00	5.E+01	2.E-01	5.E+00
Cd-109*	2.E+04	5.E+05	2.E+02	5.E+03	2.E+01	5E+02
Co-57*	7.E+02	2.E+04	7.E+00	2.E+03	7.E+01	2.E+01
Fe-55*	8.E+05	2.E+07	8.E+03	2.E+05	8.E+02	2.E+04
Ge-68*	7.E+02	2.E+04	7.E+00	2.E+02	7.E-01	2.E+01

ACTIVITIES CORRESPONDING TO THRESHOLDS OF CATEGORIES

Radionuclide	Category 1 1000 X D (TBq) (Ci)s	Category 2 10 X D (TBq) (Ci)s	Category 3 D (TBq) (Ci)s
--------------	---------------------------------------	-------------------------------------	--------------------------------

Ni-63*	6.E+04	2.E+06	6.E+02	2.E+04	6.E+01	2.E+03
Pd-103*	9.E+04	2.E+06	9.E+02	2.E+04	6.E+01	2.E+03
PO-210*	6.E+01	2.E+03	6.E+01	2.E+01	6.E-02	2.E+00
Ru-106(Rh-106)*	3.E+02	8.E+03	3.E+00	8.E+01	3.E-01	8.E+00
TI-204*	2.E+04	5.E+05	2.E+02	5.E+03	2.E+01	5E+02