Hazardous Materials and Operations

1. Hazardous Materials and Medical Waste

Lawrence Hospital has a comprehensive Health & Safety (H&S) program to address the health and safety of its employees and patients as well as to ensure compliance with the complex regulatory environment. Additionally, NYSDOH regulates medical procedures, treatment regimes, material handling, medical waste handling, and proper equipment protocols. Lawrence Hospital has developed a Hazardous Material policy as one element of its H&S program. The Hazardous Material policy includes proper procedure and protocols for regulated medical waste, municipal solid waste, recyclable waste, universal waste, and hazardous waste. See attachment F for further policy and procedures. Lawrence Hospital's Cancer Care program is accredited by the American College of Surgeons with Commendation.

2. Radiation Therapy

The Lawrence Hospital Cancer Center plans include the addition of Radiation Oncology services and the installation of two linear accelerator vaults.

Radiation oncology, also called radiation therapy, is one of the most common treatments for cancer with over 60% of patients receiving a course of radiation therapy as either their primary therapy or in combination with a regimen of chemotherapy. Radiation therapy is most commonly delivered by special equipment, called linear accelerators. This type of treatment is also known as "external beam radiation therapy" (EBRT) and, as the name implies, treatments are delivered using a high-energy beam of ionizing radiation.

Radiation therapy can be given alone or in combination with other treatments, such as surgery or chemotherapy. Unlike chemotherapy, which exposes the entire body to cancer-fighting drugs, radiation therapy is usually localized to a precise area in the body, and only affects that area. Thus, the cancer cells are damaged and unable to grow, while there is minimal harm to nearby healthy tissue.

Services at Lawrence Hospital currently include diagnostic radiology equipment including general radiography (X-ray), mammography and CT-scanners, in addition to nuclear medicine diagnostic imaging (PET). Diagnostic imaging provides a means for identifying and monitoring diseases or injuries. While there is ionizing radiation emitted in obtaining these images, the amount of radiation the patients receives is a fraction of what a patient receives in radiation therapy. The doses of radiation produced by a linear accelerator for external beam radiation therapy are approximately 3-5 times higher than

that in CT-Scans and several thousands times that of plain X-rays.

The linear accelerator uses microwave technology (similar to that used for radar and microwave ovens) to generate a beam of high-energy electrons which are “accelerated” through a series of magnets called a “wave guide”. This electron beam is then directed into a tungsten, or other heavy metal, target to produce a high-energy beam of ionizing (photon) radiation that is shaped and directed to treat the targeted tumor site.

The linear accelerator includes computer controlled device called a multi-leaf collimator to precisely shape the photon beam to match the target as prescribed by the Radiation Oncologist. The treatment beam can be directed to the tumor from multiple locations as the machine rotated around the patient, allowing the delivery of radiation from multiple directions and at varying energy levels, all specifically designed to deliver the maximum dose to the tumor site, while limiting the radiation dose to sensitive organs and healthy tissue.

The “radiation” beam produced by the linear accelerator does not involve any radioactive materials or radioactive waste products and when power to machine is switched off, the treatment beam stops immediately, just as a microwave oven does.

The linear accelerator is located inside a shielded room or “vault” which is designed to protect the treatment staff and patients in the facility, as well as any pedestrians outside the facility, from any exposure to the x-ray beam. For the Lawrence facility the treatment vault shielding is composed of a combination of concrete walls that are four (4’) feet thick at the secondary shields, and eight (8’) feet thick at the primary shields. The roof of the vaults are comprised of four and a half (4 ½’) feet thick concrete ceilings with additional lead sheets varying from 1 to 6 inches in thickness. In order to keep the basement footprint a small as possible, the width of the floor is a result of two vaults side by side with no additional ancillary space between the vaults.

The treatment vault shielding is designed by a specially licensed medical physicist to limit the exposure to staff, patients and visitors to save levels as defined by the National Council on Radiation Protection (NCRP Standard 151) and the United States Nuclear Regulatory Commission (CFR Title 10). The shielding design address all areas of potential exposure and the final design is tested and certified by the on-site radiation physicist prior to the final licensing of the machine. In addition, the current Physicist's Report will be made available to the Area Office staff of the NYS Department of Health during final inspection of the facility, and will be maintained on site as a permanent record.

The licensing and ongoing operations of the linear accelerator are governed by the State of New York Department of Health and the New York State Department of Labor and include daily, monthly and annual machine calibration and radiation safety checks.

3. Chemotherapy

The Lawrence Hospital Cancer Center will also continue to offer chemotherapy treatments. Chemotherapy, like radiation therapy may be used as the primary treatment or in combination with surgery and radiation therapy.

Chemotherapy uses a wide variety of drugs in many combinations depending on the exact nature of the disease being treated. Many, although not all, chemotherapy drugs are classified as "cytotoxic" and can be harmful if exposure levels are high enough. To safeguard non-patients and staff, and to ensure that chemotherapy drugs are not contaminated during handling and mixing, there are stringent requirements placed on the handling, mixing and dispensing of chemotherapy drugs.

These regulations are published by the U.S. Pharmacopeia (USP) and are considered the "best practice" for compounding sterile preparations, including chemotherapy drugs. While the State of New York has not formally adopted the USP guidelines, the Lawrence Cancer Center chemotherapy mixing pharmacy will be constructed to comply with this standard.

The USP standards (USP Chapter 797) for chemotherapy drug mixing require that all drugs be mixed in specially filtered bio-safety cabinets, often referred to as "hoods", which must be located in special clean rooms. The mixing hoods and the clean rooms are pressurized and include HEPA filtration for all airflow entering and leaving the room. These filters are designed to remove airborne organisms and particulates (0.3 micrometers (μm) in diameter) with an efficiency of 99.99% to maintain a sterile environment within room where the mixing hoods are located. In addition, all airflow entering and leaving the mixing hood passes through an additional set of HEPA filters to maintain the sterile environment within the mixing hood, and to filter the exhaust air.

It should be noted that Lawrence Hospital currently provides chemotherapy treatments, and drug mixing, on-site.