I. Introduction
The Hazardous Materials and Wastes Management Plan (EC.02.02.01) is an “umbrella” plan that defines the mechanisms for interaction and oversight for controlling biological, chemical, and radiological materials and wastes. The Management Plan addresses methods both to identify materials that need special handling and to prescribe processes to minimize the risk of their unsafe use and/or improper disposal. The related policies and procedures govern activities from receipt to disposal of these hazardous agents. The policies are based on regulatory requirements and are designed to ensure compliance with all Federal, State, and local regulations. This Plan applies to (scope) Duke University Hospital and Clinics, the Clinical Laboratories, the Private Diagnostic Clinics, and the Duke Primary Care practices. In addition, more hazard-specific plans are developed by function leader experts as described in the Organization of Participants discussed below.

II. Organization of Participants
The administration and oversight of hazardous materials and waste management is primarily the responsibility of the Occupational and Environmental Safety Office (OESO), with the Environmental Service Department administering the Medical Waste Management Program. Specific responsibilities are as follows:

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<tr>
<th>Hazardous Materials</th>
<th>Biological – Biological Safety Division</th>
<th>Dr. Schwartz</th>
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<tr>
<td></td>
<td>Chemical – Occupational Hygiene and Safety Division</td>
<td>Ms. Greeson</td>
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<td>Radioactive Materials/Sources – Radiation Safety Div.</td>
<td>Dr. Yoshizumi</td>
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<td>Hazardous Wastes</td>
<td>Biological - Environmental Services</td>
<td>Mr. Bass</td>
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<tr>
<td></td>
<td>Chemical – Environmental Programs Division</td>
<td>Mr. Trunzo</td>
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<td></td>
<td>Radioactive – Environmental Programs Division</td>
<td>Mr. Trunzo</td>
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III. Hazardous Materials Management (EC.02.02.01, EP 1, 3, and 12)
The responsible leader for each of the different classes of hazardous materials develops an agent-specific management plan, which is reviewed annually by the Duke University Safety Committee (DUSC). These plans identify materials that require special handling and define the specialized management practices for each hazard class, including all relevant processes for selecting, labeling, handling, storing, inventorying, using, and responding to incidents with such materials or wastes. Inventories of hazardous materials and wastes are maintained as required by applicable laws and regulations. General provisions of each plan are as follows:

A. Hazardous Biological Materials (IC.01.03.01, EP 1-3, IC.01.04.01, EP 1, and IC.02.01.01, EP 1-2) - The primary policies for managing biological hazards for healthcare employees include the Bloodborne Pathogens Exposure Control Plan and the Tuberculosis Control Plan (Section VI. of the Duke University Safety Manual). Both of these plans are subject to annual update and approval by the DUSC and the Hospital Infection Control Committee (HICC).

A.1. Integration with Infection Prevention – Based on both past experience with Biological Materials being a part of the management process for the Environment of Care (EOC) and the necessary interactions with many of the EOC functions, Biological Materials will
continue to be integrated in the overall planning and management of the EOC under the Safety Management Plan and the Hazardous Materials and Wastes Management Plan. Integration with the relevant Infection Prevention/Control standards and elements of performance will be achieved through collaboration between the DUSC and the Hospital Infection Control Committee (HICC). The Chair of the DUSC is a standing member of the HICC and the Infection Prevention and Hospital Epidemiology Department (IPHE) is represented on the membership of the DUSC. In addition, the function leaders for Biological Materials and Wastes will be invited to present appropriate updates to the HICC.

B. Hazardous Chemical Materials (EC.02.02.01, EP 1, 3-5, and 8-12; and MM.01.01.03, EP 1&2) - Management and control procedures for chemical hazards are presented in Section II.4 (Hazardous Materials), Section V. (Chemicals in Laboratories and Hazard Communication) within the Duke University Safety Manual. In addition, special precautions for managing cancer chemotherapy agents, Ribavirin, Pentamidine and other hazardous drugs are found in the Hazardous Drugs Policy (Supplement section of the Duke University Safety Manual).

The Hazardous Chemical Management Plan also references the procedures for controlling risks associated with selecting, handling, storing, transporting, using, responding to spills or incidents, and disposing of hazardous chemicals, gases and vapors, including monitoring levels of hazardous gases and vapors to determine that they are in safe ranges (EC.02.02.01, EP 9 and 10).

C. Hazardous Radiological Materials (EC.02.02.01, EP 6, 12, 17, and 18) - All procedures governing selecting, handling, storing, transporting, using, responding to incidents or spills, and disposing of radiological materials are presented in the Duke University Radiation Safety Manual, the Duke Hospital Radioactive Materials Policy, and the Division of Nuclear Medicine Policy Manual, and the Quality Control Manual for the Department of Radiation Oncology. Direct oversight of the Radiation Safety program is provided by the Medical Center Radiation Safety Committee. The Chair of the DUSC is an ex officio member of the Committee to ensure appropriate interactions and coordination.

D. Hazardous Energy Sources (EC.02.02.01, EP 7) – Safety related to hazardous energy sources, including radiation-producing equipment (clinical and research x-ray machines, electron microscopes, MRI scanners, lasers, clinical linear accelerators, etc.) is addressed in the applicable safety manuals/operating procedures and in the hazardous materials and wastes management plans. This includes management of the inventory and inspections of items of x-ray shielding garments (aprons, thyroid shields, etc.).

Results of dosimetry or monitoring badge results for all staff potentially exposed to radioactive materials or hazardous energy sources, including, including but not limited to, staff in Radiology, Cardiology, Vascular Surgery, Radiation Oncology, and Nursing are reviewed by the RSO and during the quarterly meetings of the Medical Center Radiation Safety Committee.

IV. Hazardous Wastes Management
The responsible leader for each of the categories of hazardous wastes develops a specific management plan, which is reviewed annually by the DUSC. These Plans define the specialized management practices for selecting, inventorying (as appropriate), handling, storing, transporting, using, and disposing of such wastes through use and/or final disposal. General provisions of each plan are as follows:
A. Medical Waste (IC.02.01.01, EP 6) - The Institutional policy for the Management of Medical Waste is contained in Section VII. of the Duke University Safety Manual. Additional policies governing the collection, transport, and disposal are presented in the policies of the Environmental Services Department. Employee exposure issues related to medical waste management are covered in the Bloodborne Pathogens Exposure Control Plan (Section VI.).

A.1. Integration with Infection Prevention – Based on both the past experience with Biological (Medical) Wastes being a part of the management process for the Environment of Care (EOC) and the necessary interactions with many of the EOC functions, Biological Wastes will continue to be integrated in the overall planning and management of the EOC under the Safety Management Plan. Integration with the relevant Infection Control standards and elements of performance will be achieved through collaboration between the DUSC and the Hospital Infection Control Committee (HICC). The Chair of the DUSC is a standing member of the HICC and the Infection Control Department is represented on the membership of the DUSC. In addition, the function leaders for Biological Materials and Wastes will be invited to present appropriate updates to the HICC.

B. Hazardous Chemical Waste (EC 02.02.01, EP 5 & 8 and MM.01.01.03, EP 1&2) - Chemical waste management is addressed in policies found in Section VII (Chemical Waste Management) and Supplement Q of the Duke University Safety Manual. The responsibilities for collection, storage, and disposal of these wastes is the primary responsibility of the OESO Environmental Programs Division.

C. Hazardous or Regulated Pharmaceutical (Medication) Wastes (EC 02.02.01, EP 8 and MM.01.01.03, EP 2) – Pharmaceutical wastes including their collection, storage, and disposal are a primary responsibility of the OESO Environmental Programs Division. Specific procedures for handling hazardous drugs and wastes are found in Supplement V of the Duke University Safety Manual.

C. Radiological Waste (EC.02.02.01, EP 6) - Radioactive waste management practices are addressed in the Duke University Radiation Safety Manual and the Radioactive Waste Policy (Section VII. of the Duke University Safety Manual). The responsibilities for collection, storage, and disposal of these wastes in the primary responsibility of the OESO Environmental Programs Division, with close coordination with the OESO Radiation Safety Division. Direct oversight of the Radiation Safety Program is provided by the Medical Center Radiation Safety Committee. The Chair of the DUSC is an ex officio member of the Committee to ensure appropriate interactions and coordination.

V. General Trash and Wastes (EC.02.02.01, EP 19) – The management and oversight of general trash and waste storage and timely disposal is the responsibility of the Environmental Services Department. The actual collection and transport of disposal dumpsters/roll-off is the responsibility of the Duke University’s Facilities Management Department.

VI. Incident Reporting and Emergency Response (EC.02.02.01, EP 3-4) - Emergency response procedures are presented in relevant sections of the Duke University Safety Manual and the Radiation Safety Manual. Information on reporting and managing incidents, exposures, and spills of hazardous materials are presented in the Incident Reporting and Spill Response Guide, which is available throughout the Institution.
As defined in the Safety Management Plan (EC.04.01.01, EP 8), all hazardous materials and waste spills, exposures and other related incidents are reported to OESO via the 911-notification system. This system is internal to Duke University and is managed through the Duke University Police Department’s Dispatchers. Around-the-clock response by the OESO Spill Response Team is available for all such incidents. Additionally, workers experiencing blood or body fluid exposures are encouraged to report such injuries through the 24 hour Exposure Hotline (115 or 919 684-8115, off-site) and the Safety Reporting System on-line (SRS). Potential employee exposures to TB are followed by Biological Safety Division personnel through chart review and contact of supervisors in the affected areas of exposure. Details of this response are provided in the Emergency Response Guide and the Hazardous Materials and Waste Management Plans.

VII. Performance Improvement (PI) - The administrative leader of each function is responsible for the development of Performance Improvement indicators, which are based on priorities identified by the function and the DUSC. The DUSC has the responsibility for approving the indicators, including monitors and thresholds. All PI activities are developed in collaboration with the Accreditation and Patient Safety Office to assure that the PI activities for the Management of the Environment of Care are appropriately integrated into the Institutional initiatives defined in the Performance Improvement Plan for Duke University Hospital and its Medical Staff.

All PI activity/experience is reported quarterly and this information is provided to the Governing Body through the routine reporting channels. All elements of the PI program are subject to change at any time based on Institutional experience, regulatory change, or administrative input.

VIII. Training (EC.03.01.01, EP 1&2) - Policies and procedures for selecting, handling, storing, using, and disposing of hazardous materials and wastes, as appropriate, are included in both new employee orientation and annual update training programs for the Environment of Care. Function leaders participate in the development of these training materials. The orientation programs describe the hazards, risks, regulations, and Institutional controls; while the update training programs emphasize new information on risk, program performance experience, and control procedures.

IX. Performance Monitoring

A. Departmental and Employee Performance - Departmental and employee performance is monitored during the EOC Walkthroughs, Fire Marshal inspections, and laboratory audits. Compliance with policy and employee awareness is assessed and reported to the DUSC as appropriate.

B. Hazardous Materials and Wastes Function Performance - External monitoring of the program effectiveness for each hazardous materials and wastes function is provided by the DUSC. Each function presents annual planning objectives for Committee review. These objectives are developed in accordance with the mission of the Institution, any applicable laws or regulations, and all relevant accreditation standards; and they define the focus for resource utilization for each function. Many of the objectives include measurable outcomes and, thus, establish opportunities for performance standards for the functions. In assessing the performance of each function, the DUSC selects one to three of these planning objective and evaluates the progress towards accomplishing the stated outcome. Specific performance improvement standards, when indicated, are defined in the management plans for the function, with the monitors and thresholds being approved by the DUSC.
C. Regulatory Review of Hazardous Materials and Wastes Functions (EC.02.02.01, EP 11) – Each of the hazardous materials or wastes functions is subject to external review of compliance, licensure, permits, and/or manifest documentation. Each function ensures that the necessary permits, licenses, manifests, and safety data sheets are managed in compliance with the applicable laws and regulations. Details of performance related to these responsibilities are provided in the individual management plans.

X. Management Plan Evaluation (EC.04.01.01, EP 15, IC.01.05.01, EP 2 and IC.03.01.01, All EPs) - The function leaders will evaluate their material-specific Management Plan annually for its scope, objectives, performance, and effectiveness. Any changes in scope will be addressed during the annual update of the Plan, and any changes in the range of application or interactions will be incorporated into the updated Plan. Annual planning objectives will be developed through interactions with DUSC members and hospital administration. These objectives will address the primary operational initiatives for maintaining and enhancing the “safety” of the Environment of Care. Progress toward accomplishing these objectives will be reported at least annually to the Committee as a year-end summary of the effectiveness in accomplishing these objectives. The performance of the Plan will be assessed through progress in achieving the Performance Improvement Standards defined within the Plan. The annual evaluations, updates, and planning efforts will be presented for Committee review and action during the first quarter of the new calendar year. This information will be provided to the DUH leadership and the DUHS Board of Directors through the routine reporting channels.