COUNCIL ON IONIZING RADIATION MEASUREMENTS AND STANDARDS

(CIRMS)

Second Report on

NATIONAL NEEDS IN IONIZING RADIATION MEASUREMENTS AND STANDARDS

Prepared by the CIRMS Science and Technology Committee

October 1998

Council on Ionizing Radiation Measurements and Standards

Past Presidents

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PREFACE

The Council on Ionizing Radiation Measurements and Standards (CIRMS) is an open-membership, non-profit, and action-oriented society organized for educational and scientific purposes for persons, organizations, and corporations willing to support and participate in its functions. CIRMS was incorporated in January 1993 and was recognized as being tax-exempt in March 1994 under section 501(c)(3) of the Internal Revenue Code.

The main objectives of CIRMS are advancement and dissemination of the physical measurements and standards needed for safe and effective applications of ionizing radiations. Ionizing radiations are higher-energy ultraviolet light, x rays, gamma rays, and energetic particles, such as electrons, protons, and neutrons that can ionize atoms and molecules. Examples of technological applications and additional activities that give rise to the need for accurate measurements of these radiations are:

Diagnostic Radiology
Particle Accelerators
Therapeutic Radiology
Ion Implantation
Radioisotope Imaging
Natural Radioactivity
Radioisotope Tracing
Induced Radioactivity
Nuclear Medicine
Activation Analysis
Industrial Radiography
Nuclear Reactors
Electron Microscopy
Military Applications
Radiation Processing
Radiation Dosimetry
Materials Degradation
Radiation Protection

CIRMS has been effective in coordinating the activities of federal, state, and private-sector organizations concerned with applications of ionizing radiations and the related programs of physical measurements and standards laboratories. Examples of the organizations are:

Federal Organizations—U.S. Departments of Energy, Defense, and Health and Human Services, the Nuclear Regulatory Commission, and the National Institute of Standards and Technology

State Organizations—State and local radiation control programs, and secondary calibration laboratories

Private-Sector Organizations—Hospitals, Industrial Firms, Professional and Scientific Societies, and Measurement and Standards Laboratories

By so doing, CIRMS focuses attention on current issues in measurements, standards and quality assurance in the broad field of ionizing radiations.

To accomplish its purposes, the Council functions through an annual meeting, through activities of committees and subcommittees, and through sponsorship of seminars and workshops. The officers of CIRMS are a President, First Vice-President, Second Vice-President, immediate Past President, and Secretary-Treasurer. The Executive Committee consists of these officers plus a NIST representative and an Executive Secretary, and is responsible for the executive, financial, and general administrative business of the Council. For example, the Executive Committee approves the appointment by the President of various standing and *ad hoc* committees. The standing committees are: Science and Technology, Program, Finance, Communications, Membership, and Nominating.

The members of the Executive Committee at the time it reviewed and approved this report were:

Robert M. Loesch, President
Thomas W. Slowey, 1st Vice President
George X. Xu, 2nd Vice President
Larry A. DeWerd, Immediate Past President
Anthony J. Berejka, Past President
Kenneth G.W. Inn, Secretary-Treasurer
Katy Nardi, Executive Secretary
Bert M. Coursey, NIST Representative

EXECUTIVE SUMMARY

This report was prepared by the Science and Technology Committee of the Council on Ionizing Radiation Measurements and Standards (CIRMS). This is the second report in this series. The first report, published in January 1995, identified 22 measurements and standards needs in four general areas: medical applications, public/environmental radiation protection, occupational radiation protection, and industrial applications and materials effects.

This report was widely distributed and had an important impact on strategic planning for CIRMS members. It is particularly true in the government sector that resources continue to shrink while new challenges for increased measurement services continue to expand. Thus, it is beneficial for government, industry and academia to work together to identify and prioritize the most important needs. The first CIRMS National Needs Report in 1995 proved that this organization could be effective in coordinating this national effort. One of the top needs identified in the 1995 report was the need for x-ray standards for mammography. This work was accomplished in a collaborative effort between the FDA, NIST and the University of Wisconsin. This example was used by the NIST in a presentation to the House Science and Technology Subcommittee in 1995 (see Appendix A).

In reviewing progress on the 22 original MPDs, it was found that success depended on three factors. First, programs that moved the fastest involved three or more institutions with a strong need for the technical work. Second, a focus workshop organized by one of the four subcommittees was very effective in forging agreements that could advance the work. (Thirteen focussed workshops were held over the last four years.) And third, a roadmap or timeline that established milestones for the collaborators was most effective in keeping the project on track.

In the present report we have identified 25 Measurement Program Descriptions (MPDs) that require concerted efforts from industry, government and the academic community. Each MPD describes a measurement-related need, a possible solution, and the impact of that solution. Details are provided regarding the technical nature of the solution, relationship to existing programs, technical opportunities, challenges and goals. Resources available and those needed to accomplish the programs are also indicated. Each subcommittee has identified one MPD for which a roadmap is considered essential to meet national goals.

Several conclusions can be made with respect to the national program:

1. There is a steady growth in the need for ionizing radiation measurements and physical standards due to the continued increase in the applications of radionuclides and ionizing radiations.

2. The effort to meet the needs of the user communities for new measurements and standards requires strong collaborative efforts with NIST on the part of medical, industrial, academic and government researchers.

3. CIRMS is playing an important role in coordinating some of the activities that must be conducted to improve the status of measurements and standards in the United States.

INTRODUCTION

CIRMS is intended to serve as a proactive forum that provides national leadership, focus, action, and information dissemination across numerous ionizing radiation disciplines on a wide range of ionizing radiation measurements and standards topics. CIRMS is the U.S. council that speaks for radiation measurements and standards issues and helps in the national and international standards developing groups to bring consensus, consistency, and common applications to industry, academia, the medical community, and government needs.

Some of the methods used by CIRMS to communicate with the user community include: the CIRMS Newsletter, the CIRMS Webpage [http://www.cirms.org], e-mail bulletin boards, generic flyers, news releases, and the issuance of periodic updates of the report on National Needs in Ionizing Radiation Measurements and Standards.

CIRMS also interfaces with users of ionizing radiation measurements and standards through the convening of annual meetings, establishing liaisons with other related organizations, developing focused subcommittees, and coordinating activities with appropriate federal and state agencies.

The present report was prepared by the Science and Technology Committee. At the time of writing, the members of this committee and its subcommittees were:

Chairman: Joseph C. McDonald, Pacific Northwest National Laboratory
Subcommittee Chairs:
H.T. Heaton, Center for Devices and Radiological Health (Medical)
D.E. McCurdy, Yankee Atomic Electric Corp. (Public/Environmental)
K.L. Swinth, Swinth Associates (Occupational Radiation Protection)
J.P. Farrell, Brookhaven Technology Group (Industrial Applications)

"We would also like to acknowledge the members of the subcommittees who contributed to the development of the MPDs during discussions at the workshops."

The members of the Science and Technology Subcommittees at the time of writing of this report were:

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MEASUREMENT PROGRAM DESCRIPTIONS

The measurement needs are presented in a standardized format called "Measurement Program Descriptions" or MPDs. (See Appendix B). Each MPD has four basic components:

First, a brief title, that identifies a measurement-related need and the radiation-related area of concern where the need exists. Both the need and the area of concern are named (for example: the MPD titled "Absorbed-Dose-to-Water Standards for Photon External Beam Radiation Therapy"). In this example, the need is for national absorbed-dose-to-water standards, and the area of concern is the medical specialty of radiation therapy.

Second, a Program Summary gives a general description of the need, proposed actions that would satisfy the need, and the resulting impact that they would have. This Summary can include background and criteria that can be used for establishing program significance, such as the number of people or size of the industry impacted, number of procedures per year, value of the service or product involved, availability and capabilities of technicians and funds to fulfill needs at primary and secondary standards laboratories.

Third, Detailed Program Characteristics are a detailed technical description of both the measurement need and the proposed solution. In the descriptions of the measurement needs, consideration was given to the following four measurements and standards areas and a possible CIRMS role:

Instruments
Radiation source fields
Dosimetry
Written procedures
CIRMS role

Fourth, recommendations are made of agencies, laboratories, and funding sources to satisfy the measurement needs identified above. The specific details of achieving these goals are also outlined in "Road Maps" that give an overall plan and timeline for the Measurement Programs. This report includes only one Road Map for each of the four subcommittees. However, Road Maps have been prepared for most of the MPDs, and these are available from the chair of the subcommittee.

The MPDs described in this report are enumerated in sequential fashion with the letter codes assigned to each subcommitee. A decimal suffix, e.g. A2.1, refers to a revision and update of an MPD which appeared in the 1995 First CIRMS Needs Report.

A. MEDICAL MPDS

INTRODUCTION TO MEDICAL MPDS

One of the oldest applications of ionizing radiation is in the area of medicine. In 1895 Roentgen discovered x-rays and within a few days the first diagnostic application was carried out as he took a radiograph of a hand. As the medical use of x rays developed, x-ray tubes became specialized for either diagnostic or therapeutic applications. For diagnostic radiology the tubes had to be designed to handle the high instantaneous energy input from small focal spot tubes, while therapy tubes had to be designed to generate much higher average energy levels for longer periods of time using larger focal spots. To treat tumors at greater depths in the body with external radiation, high-energy accelerators and radionuclide teletherapy units were pioneered in the late 1940s and 1950s.

Like x-rays, the radium discovered by the Curies in 1898 was quickly used as a therapeutic agent for the treatment of cancer. Radium brachytherapy sources were used for the interstitial treatment of tumors. Newer radionucides, e.g., ^{192}Ir and ^{125}I, have replaced radium for this use. Radionuclides are also used for diagnostic information, e.g., ^{99m}Tc is commonly used for many nuclear medicine procedures.

Historically the National Bureau of Standards (now National Institute of Standards and Technology [NIST]) played a major role in developing national standards for measuring the radiation used to treat patients. In the 1920s, the free air chamber was designed to measure the then-new radiation quantity exposure. Free air chambers with different dimensions were developed to cover the energy range from 10 to 300 keV. In the 1970s graphite cavity ionization chambers were developed to measure the exposure from ^{137}Cs and ^{60}Co. As a result of the MPD in the original "Needs" document, absorbed dose to water using a water calorimeter has been developed. This will allow NIST to provide an absorbed dose to water calibration factor for ion chambers immersed in water phantoms.

DIAGNOSTIC RADIOLOGY

The national attention to health care and the goal of universal coverage have highlighted the need for cost effectiveness and quality assurance in the care provided to every U.S. resident. Breast cancer is the second leading cause of death by cancer in women. During their lifetime, one in nine women will develop breast cancer. The Center for Disease Control estimates that breast cancer mortality could be reduced by 30 percent if all women were screened regularly. The best way to prevent deaths from breast cancer is

early detection. The best methods of early detection are self-examinations coupled with periodic mammograms. The goal of the Mammography Quality Standards Act (MQSA) was to provide high quality mammograms with the least radiation exposure. When MQSA was passed in 1992 there were no national standards for x-ray tubes commonly found in mammography units. The need for developing mammography air kerma standards was one of the four medical subcommittee MPDs in the first "Needs" report. This MPD (A1—see Appendix) proved highly successful. It was the first MPD to be completed. As a result, national standards are now available for air kerma measurements from molybdenum and rhodium anode x-ray tubes. A network of secondary level laboratories is in place for calibrating the instruments that FDA inspectors use in their yearly inspection of mammography facilities, and for calibrating the instruments that medical physicists use in their yearly on-site evaluations of mammography facilities.

Most diagnostic x-ray exams are carried out at x-ray potentials between 80 and 120 kV and use filtration typical of the NIST moderately filtered (M) series of x-ray beams. However, NIST does not offer either the M80 or M120 beams as standard options. Because of the importance of these beams for diagnostic instrument calibration, a new MPD (A5) is recommending that NIST develop these beams.

THERAPEUTIC RADIOLOGY

One of the leading causes of death of Americans is cancer—over 25% of the population will die from some form of this disease. Ionizing radiation is one of the common treatment modalities, with over half of all cancer patients undergoing ionizing radiation treatment either for palliation or for cure (approximately 600,000 patients per year). The cost of these treatments is over $10 billion per year. The goal of radiation therapy is to kill the cancer while sparing normal tissue. This means using large doses of radiation that must be accurately known and precisely delivered to the tumor. Radiation oncologists have been able to see clinically acceptable differences in the treatment of patients for variations as little as 5% in the delivered dose.

By far the most common types of radiation presently used to treat cancers are photons and electrons. Both are most frequently produced by electron linear accelerators, although radioactive source teletherapy units still play a role for photon treatments. Photon-emitting radionuclides are the primary source of photons for brachytherapy treatments. Other types of radiation used include protons, neutrons, and heavy ions. These latter radiations have features that make them desirable for treating some forms of cancer. For example, as protons are slowed down in tissue, they lose more of their energy per unit length just before they stop. Thus protons can be used to deliver more dose to the tumor and less to the surrounding tissue.

Historically the ion chambers used to measure the output of machines used for radiation therapy were calibrated free in air in terms of a exposure (or more recently air kerma)

from a ^{60}Co unit and then using a protocol to convert the measurement to absorbed dose to tissue. A more straight forward approach would be to calibrate the ion chamber in a water phantom in terms of absorbed dose to water since this is reasonably close to the desired absorbed dose to tissue. Thus there was an MPD in the last "Needs" report (A4) for developing an absorbed dose to water standard based on a water calorimeter. The revised MPD (A4.1) is nearly complete.

The biggest new application of radiation in therapy is to investigate its role in preventing restenosis following balloon angioplasty. Approximately 40 percent of patients having angioplasty have a re-clogging of the arteries within six months. There are studies that show that doses of 10 to 30 Gy are effective in preventing restenosis. In theses studies radioactive sources are inserted into the artery through a catheter. These sources are in close proximity to the vessels so the determination of the dose at millimeter distances from the source is important. Methods to calibrate these sources at close distances are addressed in a new MPD (A7).

The need for high spatial resolution dosimetry in radiation therapy is important both for verifying the predicted dose distribution calculated using radiation therapy planning software particularly for multi-leaf, rotational arc treatments and for cases where one needs to know the dose distribution near brachytherapy sources. A revised MPD (A3.1) identifies the needs for several of solid state systems capable of producing the required resolution.

With the development of improved methods of implanting brachytherapy sources in a precise manner for treating prostrate cancer, there has been a tremendous growth in the use of ^{125}I seeds for this modality. The lack of air kerma strength standards for these and other brachytherapy sources such as ^{103}Pd has slowed the implementation of the AAPM Task Group 43 report recommending the use of air kerma strength rather than activity for calibrating these sources. A new MPD (A6) identifies the program needed to develop national standards for at least some brachytherapy source calibrations in terms of air kerma strength.

NUCLEAR MEDICINE

Nuclear medicine, the use of radioactively labeled pharmaceuticals in diagnostic and therapeutic applications, has undergone enormous growth since its introduction in the late 1940s. The needs for radioactive standards used in both diagnostic and therapeutic nuclear-medicine applications is the subject of the revised MPD A2.1.

Diagnostic applications for *in-vivo* imaging have grown to 8.2 million procedures annually in the U.S. The chief reason for its continued growth is that radionuclides provide physiological information, as opposed to anatomical information (e.g., differences in tissue density) provided by the more common diagnostic x rays and magnetic resonance imaging (MRI). It has been estimated that over 80% of these diagnostic nuclear medicine procedures involve the use of six-hour half-life ^{99m}Tc. A

score of other gamma-ray emitting radionuclides with half lives from a few minutes to a few days account for the other 20 percent. Some of the most prevalent procedures involve coronary imaging, tumor imaging, renal function studies, and skeletal imaging. Appropriate ^{99m}Tc-labeled radiopharmaceuticals have been developed for these and many other applications.

A second class of radionuclides used in diagnostic nuclear medicine are the short-lived positron emitters used for positron emission tomography (PET imaging). These include ^{11}C (20 minutes) and ^{18}F (2 hours), which are ideal because of the ease with which they can be incorporated into biomolecules. The use of PET is somewhat limited at present because of the large capital investments needed in the PET camera and in the on-site cyclotron to produce the radionuclides.

Therapeutic application of radiopharmaceuticals with curative intent has been practiced since the early 1950s, mainly with ^{131}I and ^{32}P. There are presently about 60,000 nuclear medicine procedures performed per year using radionuclides for therapy. There is considerable current interest in the radiation oncology community and the private-sector radiopharmaceutical industry in developing radiolabelled monoclonal antibodies with, for example, the beta-particle-emitting nuclides ^{90}Y and ^{186}Re, used in tissue-specific agents for targeting the primary tumor.

Finally, an exciting new area is palliative radiopharmaceuticals for use in treating pain associated with bone metastases in the later stages of several types of cancers. It is estimated that up to 125,000 cancer patients per year would benefit from treatment with these bone palliation agents. Some of the nuclides already available or under investigation include ^{32}P, ^{89}Sr, ^{117m}Sn, ^{153}Sm, and ^{186}Re.

The following MPDs address measurement and standards needs in medical applications of ionizing radiation:

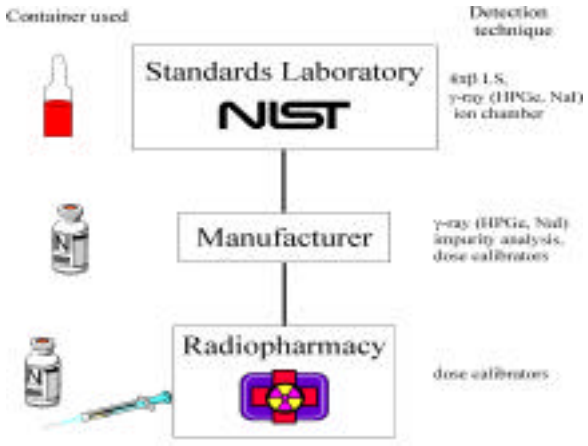
- A.2.1 Radioactivity Standards and Techniques for Nuclear Medicine
- A.3.1 High Spatial Resolution Solid State Dosimetry for Radiation Therapy
- A.4.1 Absorbed-Dose-to-Water Standards for Photon External Beam Radiation Therapy
- A.5 Air Kerma National Standards for Diagnostic X-ray Beams
- A.6 National Air Kerma Strength Standards for Brachytherapy Sources
- A.7 Standardized Dosimetry for Intravascular Brachytherapy Sources

MPD A.2.1: RADIOACTIVITY STANDARDS AND TECHNIQUES FOR NUCLEAR MEDICINE

Program Summary

One of the significant components of the Supporting Chemistry Documentation accompanying New Drug Applications (NDAs) for FDA approval of new radiopharmaceuticals is the demonstration of a method of accurately measuring the activity. Levels of not only the primary radionuclide but also of any radioactive impurities present in the drugs must be traceable to the National Institute of Standards and Technology (NIST). This conformance could come in the form of the use of radioactivity solution standards distributed by NIST or in the use of NIST-determined settings for existing monitoring devices such as re-entrant ionization chambers ("dose calibrators"). In some cases the decay properties (half-life, decay probabilities, decay energies) of the particular radionuclide under investigation may be poorly known. These data are crucial to the development of a radionuclide standard. Moreover, use of a consistent set of decay data by all laboratories and clinics is needed to ensure compatible results.

Involvement by NIST at an early stage in the development of new radiopharmaceuticals can help provide the information necessary to ensure more rapid approval of those drugs. In the case of ^{89}Sr, the only radiopharmaceutical for use in bone pain palliation therapy, the time between initial application and subsequent approval was an unacceptable 13 years. The program outlined below is aimed at enabling faster licensing of new radiopharmaceuticals.



A.2.1¾ Standards and measurements for radiopharmaceuticals at three levels in measurement chain.

Of course, the most important impact of this program is increased safety to patients undergoing various radiological procedures. In a recent Institute of Medicine report, it was estimated that over 13,000,000 diagnostic procedures (including PET, SPECT) using radionuclides are performed every year in the U.S. and an additional 200,000 radiotherapeutic procedures are performed every year. Through the activities outlined in this Program, more accurate and consistent measurement of the amount of activity administered to the patient can be achieved. Additional developments will push the current limits of sensitivity of detection equipment, allowing more accurate diagnoses to be made with less radiation exposure to the patient.

Detailed Program Characteristics

Radioactivity standards for nuclear medicine in the United States are based on measurements made at NIST. Each new radionuclide poses unique problems depending on the half-life, decay scheme, chemical properties, and radionuclidic impurities. NIST has developed standards for different radionuclides for nuclear medicine, but requires new resources to meet the demands of an expanding nuclear medicine field and increasingly sophisticated technology requirements. Currently, U.S. laboratories report that they are producing or investigating three dozen or so radiopharmaceuticals for which the data used for assay may be suspect.

Development of solutions to the various challenges outlined above can be organized as follows:

Provide standards for new radiopharmaceuticals in the following areas:

1. Electron-emitting Therapeutic Radionuclides: Provide standards for ^{177}Lu, ^{64}Cu, ^{67}Cu, and ^{195m}Pt.

2. Alpha-emitting Radionuclides for Therapy: There has been much interest lately in the use of alpha-emitting radionuclides such as ^{212}Bi, ^{213}Bi, and ^{211}At in radioimmunotherapy treatment for micrometastatic cancer, AML (acute myeloid leukemia), and other diseases which can be treated by targeting single cells. Other applications being considered include use in synovectomy and in stents to prevent restenosis after angioplasty. The challenges posed by these radionuclides arise from the fact that the measurements are now carried out over an entire decay chain of 2-4 daughters, all with different and - decay branching ratios, and also the fact that these radiopharmaceuticals are produced by separating U or Th isotopes.

3. Diagnostic Radionuclides:

   a. Characterization of new radiopharmaceuticals being developed for PET and SPECT work such as ^{62,64}Cu and determination of dose calibrator settings.

   b. Re-evaluation of dose calibrator settings for the radionuclides currently in use for Positron Emission Tomography. This would include the widely-used ^{18}F, ^{11}C, ^{13}N, and ^{15}O.

Because most radionuclides currently in use or under investigation for use in nuclear medicine emit radiations that can be detected with high efficiency using liquid scintillation (LS) spectrometry, this method is becoming more widely used as a way to quantify these radionuclides. Due to the complex chemistry associated with this technique, though, there are many effects that could inhibit the ability to make accurate measurements, therefore, research into such effects should be pursued.

Additional goals of this project include:

- Accurate measurements of decay data of the radionuclides being developed for medical use and for daughters encountered in the subsequent decay chains.
- Develop rapid methods for assaying radionuclides used in intravascular brachytherapy. This will present a great many challenges due to the unique source geometries often used in this treatment modality.
- Develop methodologies for rapid determination of administered activity through and spectrometry.
- Develop triple-coincidence standards for use in the more sensitive higher-fold coincidence detectors.

U. S. Facilities, Staffing, and Funding

1. Standards Laboratories: NIST can provide activity measurements to better than 1% and can provide impurity analyses. Facilities are also available for physical decay property measurements. The program continues to be very active. However, expansion in terms of equipment and manpower is needed to keep pace with the demands of a rapidly-growing industry.
2. Manufacturers: Amersham, DuPont Merck, Bristol-Myers Squibb, and many other manufacturers have systems in place to accurately assay the bulk radionuclides, and they can demonstrate traceability to NIST by inter-comparisons through the NIST/NEI radiopharmaceutical program. This program will distribute standard reference materials for ^{89}Sr, ^{90}Y, ^{153}Sm, and others as determined by the industry. Wider participation in the program by instrument manufacturers and hospitals can provide better measurement quality assurance at all levels.
3. Radiopharmacies: If the nuclide emits gamma-rays, it must be assayed prior to administration in a calibrated dose calibrator. If it only emits alpha- or beta-particles, the pharmacy will most likely rely on the manufacturer's assay, although liquid scintillation or similar methods, if available could also be used as a confirmation.

Goals: This program is focused on the accurate assay of medical radionuclides and wider use of consistent measurement quality at all levels. This can be achieved in three ways: (i) new standards, (ii) development of new techniques and equipment, (iii) measurement and dissemination of nuclear data.

Progress on MPD A2.1 Since Publication of 1995 Needs Report

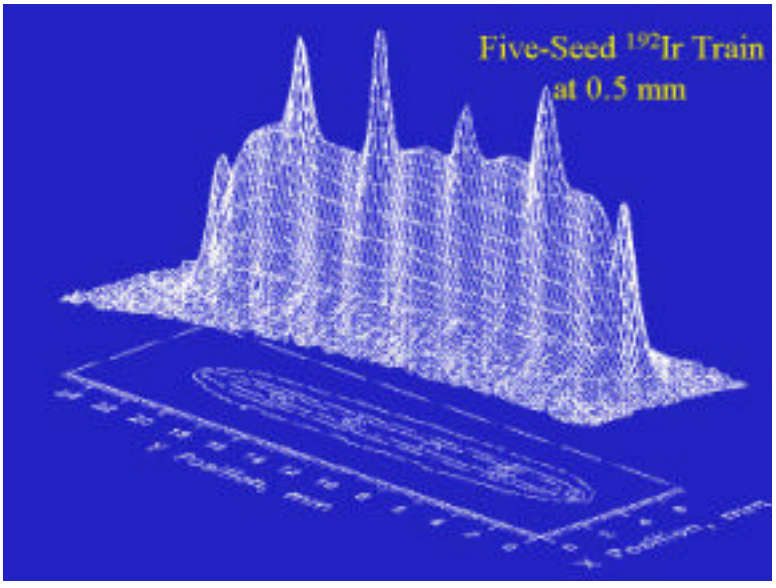
The CIRMS Medical Subcommittee held a workshop on needs for standards and measurements for radionuclides used in bone palliation in September 1996. Papers from this workshop were published in a Special Issue of Applied Radiation and Isotopes, Volume 49, April 1998. New standards were described for ^{89}Sr and ^{117m}Sn, both of which were needed since commercial radiopharmaceuticals for these nuclides are now available. Progress was also reported for ^{62}Cu a new radionuclide for use in Positron Emission Tomography (PET) imaging. This nuclide, which has a half life of only 9.67 minutes is obtained from a commercial ^{62}Zn-^{62}Cu generator. The cyclotron-produced parent ^{62}Zn has a half life of 9 hours.

MPD A.3.1: TWO- AND THREE-DIMENSIONAL DOSE-MAPPING SYSTEMS FOR RADIATION THERAPY

Program Summary

In order to increase the efficacy of radiation therapy by minimizing the dose to normal tissues and increasing the dose to tumors, highly complex treatment modalities are being introduced into clinical practice. Under the general heading of "conformal therapy", these modalities include the moving, non-coplanar x-ray beams used in stereotactic radiosurgery, the Gamma Knife also used for radiosurgery, dynamic multi-leaf collimators, intensity-modulated beams, etc. In addition to these types of external-beam therapy, where spatial resolution of 1-2 mm may suffice, techniques for the measurement of the dose distributions produced by radioactive sources used for interstitial tumor implants and the treatment of restenosis are required. The resolution required for these applications will be on the order of tenths of millimeters. In order to confirm that the computer-generated dose distributions used for planning these treatments are accurate, there is a critical need for the development and evaluation of dose-mapping systems capable of providing high-resolution dose distributions in two and three dimensions.

The basic dosimetry of all radiation sources is done with ionization chambers. Although ionization chambers are mainly used to measure doses at specific points, they are also employed singly or in multi-chamber arrays in water-tank scanners for the mapping of static, external beams. The rectangular shapes of the water tanks and physical constraints of the scanning mechanisms restrict their range of applications. Depending upon the size of the ionization chamber, resolution on the order of 2 mm can be obtained, and this can be improved by the replacement of the ionization chamber by a submillimeter diode detector. Water-tank scanners are not applicable to the mapping of dose distributions produced by the dynamic beams used in conformal therapy.



A.3.1¾ Autoradiograph of a series of iridium-192 seeds taken with radiochromic film dosimetry medium. The film was readout on a scanning densitometer with a 632 nm HeNe laser.

Silver-halide films have been widely used for mapping dose distribu-

tions, but they suffer from a limited dynamic range which plateaus at about 1 gray, an energy dependent dose response, which depends upon the conditions of development, and an extreme sensitivity to light and Cerenkov radiation. Because of their need for light-tight envelopes, silver-halide films are difficult to use in anthropomorphic phantoms.

There are other systems under development or being evaluated that individually or in combination may meet the requirements for accurate, high-resolution dose mapping. These include radiochromic films, radiochromic gels, photostimulated luminescence films, thermoluminescent films, polymer gels and alanine films.

Radiochromic dyes exhibit a color change that is proportional to absorbed dose, and these color changes may be measured with an optical densitometer. Radiochromic dyes have been incorporated into tissue-equivalent films and into tissue-equivalent gels for recording three-dimensional dose distributions. Radiochromic gels require a computerized tomographic optical scanner for read out. To obtain dose distributions that are consistent to within 2-3%, radiochromic films require doses in excess of 10 Gy, and radiochromic gels may require 4-5 times this level.

Thermoluminescent dosimeters (TLD), in the form of rods or chips having millimeter dimensions, have long been used to measure relative dose distributions. They have a wide dynamic range and, with careful use, 1-2% reproducibility can be achieved. Differences in atomic composition between the TLD's and the medium of interest can lead to a response that is dependent upon the radiation energy. Measurements require a TLD reader dedicated to this application. The measurement of a dose distribution using TLD rods or chips is a tedious procedure, one rarely undertaken outside of the research laboratory. TLD's distributed on films have recently become available, and this development could provide competition to silver halide and radiochromic films. The laser-scanning readout device is not yet commercially available. Resolution of current TLD films is on the order of 3 mm, however, laboratory data indicate that with further development this can be increased by two orders of magnitude.

Photostimulated luminescence systems include 8 inch by 10 inch imaging plates and readers capable of 100 μm pixel resolution are commercially available. The high-z phosphors employed are not suitable for low energy photon sources, but the high dynamic range (7 decades) are quite useful for generating large amounts of information is single exposures.

Polymer-gel dosimeters are tissue-equivalent and record dose distributions in three dimensions. The gels consist of acrylic monomers dispersed in a gelatin matrix. Radiation-induced polymerization of these monomers results in a dose-dependent change in NMR and optical scattering properties of these gels. The sensitivity of the gel may be adjusted to meet specific requirements, and maximum doses are in the range of 5-20 Gy. The resolution of dose distributions is limited mainly by the read-out device

employed; 1-2 mm using large-field MRI or the optical scanner, and sub millimeter using small-bore, high-field MRI designed for small-animal research.

Detailed Program Characteristics

The candidate systems must be characterized in terms of dose-response curves, dose-rate and radiation-energy dependence, resolution, tissue equivalence, signal lifetime, temperature and humidity dependence, etc. (This characterization should take account the intrinsic resolution of the dosimeter, as opposed to the system resolution, i.e., dosimeter plus readout device, because the readout device may be the limiting factor but one subject to improvement.) So as to obtain comparable data, it is critical that each system be irradiated by the same source, one whose dose distribution in water or a tissue-equivalent medium has been firmly established.

The acceptable level of spatial resolution of a dose-mapping system is determined by the irradiated volume under consideration. In general, this will depend upon the distance over which the dose distribution drops from its maximum to about 10% of that value. For high-energy x-ray beams this distance increases with depth due to the side scattering of both photons and secondary electrons, and may be less than a centimeter at the surface but as much as two centimeters at 10-cm depth. For radioactive sources, a decrease in dose by a factor of ten can occur within a matter of millimeters from the source. Therefore, the resolution of a dose mapping system to be applied to radioactive sources must be considerably higher than one to be applied to x-ray beams. A system's resolution may be defined in terms of the smallest distance over which it is intended to measure doses that decrease by a factor of ten, and that this resolution should not be greater than 10% of this distance.

Other organizations such as the AAPM should define the appropriate clinical applications for each system. The Task Group of this organization may have to consider one or more phantoms that are suitable for specific systems and also satisfy clinical requirements. Also this Task Group would evaluate each system as applied to its most appropriate clinical problems.

Summary of Measurements Needed

Benchmarking is needed against other dosimetry systems used for similar purposes. Four treatment modalities that should be investigated at major US medical facilities are: the ^{60}Co Gamma Knife, proton beams, stereotactic accelerator photons, and a variety of sources used in brachytherapy. These are four areas in radiation therapy where 2- and 3-dimensional dose maps would be of immediate aid in therapy planning.

U.S. Facilities, Staffing and Funding

1. NIST: NIST has extensive experience with the use of radiochromic dosimetry systems for high-dose applications such as radiation processing and sterilization. To extend these systems for use in dose mapping, NIST has acquired a laser scanning microdensitometer. This has become the *de facto* standard for reading radiochromic films, but several other film readers are under evaluation. NIST would need to develop appropriate readout capabilities for other identified dosimetry systems.

2. Manufacturers: The manufacturers of the various dosimetry systems would need to provide samples that could be irradiated under a set of standardized conditions.

3. Professional Organizations: A Task Group of some professional organization, e.g. the AAPM, would have to be setup to address the use of these dosimetry mapping systems and develop appropriate criteria for specification of the system resolution capabilities.

4. ADCLs: After the dosimetry systems have been evaluated, it would be desirable to develop a mechanism to maintain control over the quality of dosimetry systems used in clinical practice. This could be accomplished by having one or more of the Accredited Dosimetry Calibration Laboratories of the AAPM provide standard irradiations and readouts of the developed dosimetry system.

Progress on MPD A3.1 Since Publication of 1995 Needs Report

The major progress in high-resolution imaging since 1995 has been under the framework of the AAPM Task Group 55: Radiochromic Dosimetry: Recommendations of the Radiation Therapy Committee. Several CIRMS members served on the Task Group that prepared recommendations for clinical physicists on the use of radiochromic film for medical applications. This report, which has been approved by Therapy Committee for submission to medical Physics, includes sections on historical development, physical and chemical description of radiochromic systems, scanners and instrumentation, and application of radiochromic film in clinical dosimetry. This report was limited to radiochromic film and concentrated on 2D imaging applications.

MPD A.4.1: ABSORBED-DOSE-TO-WATER STANDARDS FOR PHOTON EXTERNAL BEAM RADIATION THERAPY

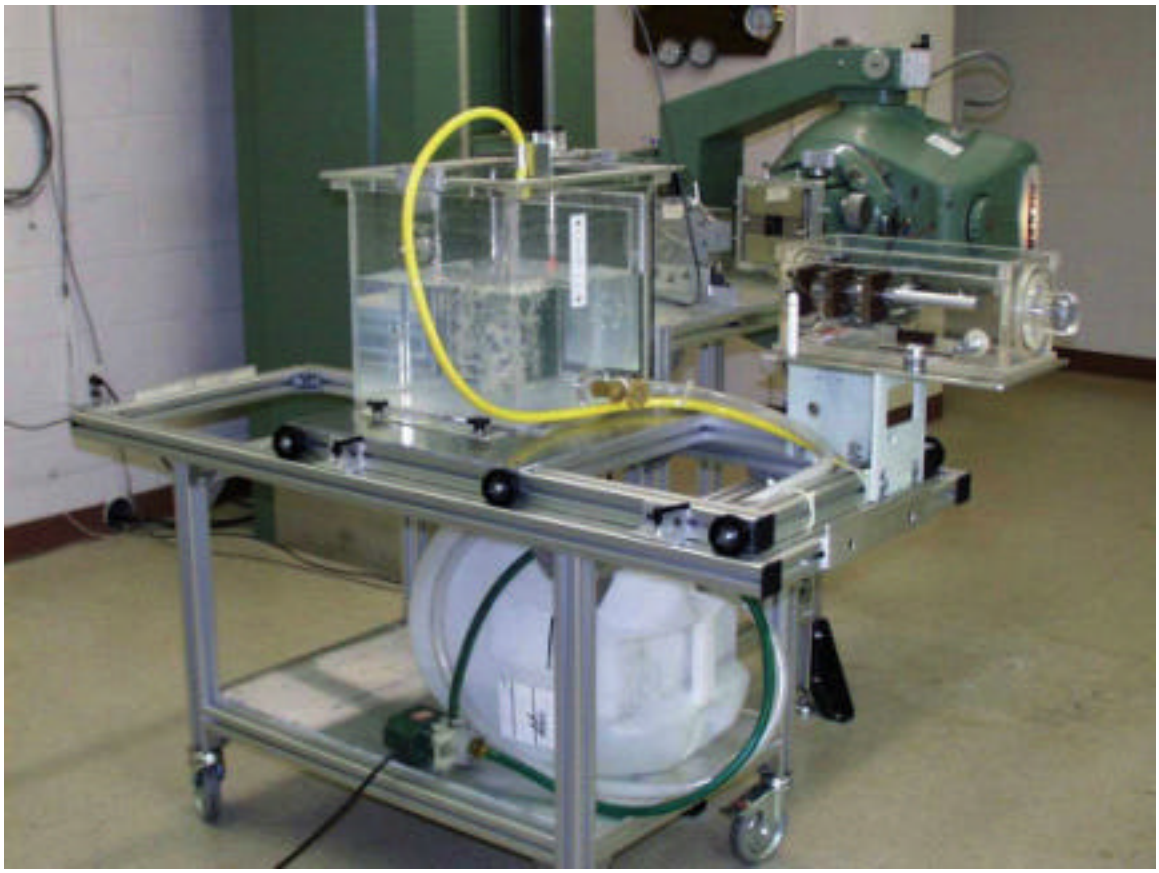
Program Summary

Approximately 500,000 cancer patients are treated annually in the United States with high-energy electron or photon beams from electron accelerators or at a diminishing number of ^{60}Co teletherapy units. These treatments are given at approximately 1300 radiation therapy facilities, using about 2000 high-energy accelerators. These facilities are required to have an ionization chamber to measure radiation doses and calibrated at least once every two years at one of the AAPM Accredited Dosimetry Calibration Laboratories (ADCLs), or at NIST.

Radiation therapy has been practiced in the U.S. since the turn of the century. In the 1930's photon beam energies available for use in radiation treatment were only a few hundred thousand electron volts. The national standard was a free-air ionization chamber, and the quantity measured was exposure. With the advent of ^{60}Co 1.25-MeV gamma-ray beams, a Bragg-Gray cavity ionization chamber was used to realize the quantity exposure. However, as it is impractical to measure the quantity of exposure at energies over 2 MV, and since this quantity does not apply to electron beams, the concept of absorbed dose was introduced. The unit of absorbed dose (energy absorbed per unit mass of irradiated material) is the gray (Gy). This quantity can be used to specify the dose to any reference material from any source of radiation. Historically, professional organizations such as the AAPM have developed protocols for determining absorbed dose delivered during a radiation treatment based on an ion chamber calibration for exposure in a ^{60}Co beam. NIST, however, has offered an direct absorbed dose calibration based on a graphite ion chamber.

Due to the complexity of protocols based on exposure (or air kerma) calibrations, it is much more desirable to have a direct absorbed dose to water calibration. The most direct way to measure the absorbed dose to water is to use a calorimeter. There has been much work on this method. Early work on a practical, reliable and accurate absorbed dose to water calorimeter for ^{60}Co, 4-25 MeV photon beams and 160 MeV proton beams was developed at Yale University in the late 1980's. In 1993 NIST completed extensive development of an absorbed dose water calorimeter. This standard detector system can realize the quantity absorbed dose for both ^{60}Co beams and, in principle, higher energy photon beams. It will now be possible for NIST to offer calibrations to the secondary laboratories of the AAPM which are closer to the conditions needed for calibrations at existing therapy facilities.

The changeover from in-air calibrations for the quantity air-kerma to in-phantom absorbed dose calibrations is a logical and necessary evolutionary step in radiation dosimetry. Nevertheless, the pathway to the new standard must be carefully planned to



A.4.1¾ Water phantom set up for absorbed dose to water measurements at the K&S Accredited Dosimetry Calibration Laboratory.

avoid confusion for the end users. The foremost goal must be to make the new standard system logical, straightforward, and as simple (and familiar) as possible for the medical physicist in the hospital. Such a system can alleviate problems with current practices. There are task groups of the AAPM addressing the questions involved for the application of the quanity absorbed dose in water.

Detailed Program Characteristics

The program has several components. Some of these can proceed independently, but there is a logical sequence for the following steps.

1. Characterization of the standard detector (calorimeter) and reference source (^{60}Co) at NIST.

2. In-phantom measurements of reference ionization chambers for the ADCLs at NIST and in-phantom measurements at the ADCLs at the ^{60}Co beam quality.

3. Preparation of a new protocol (to replace AAPM TG#21) for use by therapy facilities, which instructs the medical physicist on the use of the absorbed dose calibration factor.

Summary of Measurements Needed

Measurements the Domen water calorimeter should be documented. Other critical measurements include:

- Measurements of the parameter k_Q, which is the ratio of two calibration factors, the absorbed dose calibration factor for an accelerator beam of quality Q to that for a ^{60}Co reference beam. The values need to be documented for each type of ionization chamber in use in reference measurements.
- A round-robin of absorbed dose in-phantom measurements at ^{60}Co energies by NIST and all of the ADCLs.
- An intercomparison involving NIST and other national laboratories.

U.S. Facilities, Staffing, and Funding

1. NIST: NIST has available reference sources of ^{60}Co, a high-energy electron accelerator (the MIRF), the prototype Domen absorbed dose water calorimeter, and staff who can contribute to the project.
2. U.S. Medical Centers: Several U.S. medical centers have expressed interest in measurements with absorbed dose calorimeters. These include the two leading proton therapy centers: Harvard–Massachusetts General Hospital and Loma Linda University Hospital. Strong experimental and theoretical collaborations are also expected with Yale University and the National Research Council–Ottawa.
3. ADCLs: At present the ADCLs use ^{60}Co sources to perform in-air calibrations in terms of kerma for the therapy facilities. Initially, they could offer absorbed dose calibrations in-phantom based on their present ^{60}Co sources.

Progress on MPD A4.1 Since Publication of 1995 Needs Report

Considerable progress has been made recently on experimental intercomparisons and organizational details for implementing new absorbed dose to water standards. NIST has completed absorbed dose intercomparisons with the BIPM and the National Research Council–Canada. Both laboratories employ calorimeters of slightly different design than the NIST Domen calorimeter. NIST has also provided calibrations in terms of the new absorbed dose standard to the AAPM Accredited Dosimetry Calibration Laboratories (ADCLs). Additionally, the AAPM Task Group 51, with assistance from many CIRMS members (including two past-presidents), has prepared a new protocol for absorbed dose calibration factors for high-energy therapy beams.

A document outlining the methodology to be used by the ADCLs for such calibrations has been completed and the ADCLs have carried out a proficiency test with NIST.

MPD A.5: AIR KERMA NATIONAL STANDARDS FOR DIAGNOSTIC X-RAY BEAMS

Program Summary

NIST has long had a set of reference x-ray beams for radiation therapy. The most commonly used are the moderately filtered beams (M series). However, there are no M80 or M120 beams that define the region of the most common beams used in diagnostic radiology. Several of the American Association of Physicists in Medicine ADCLs have attempted to establish their own "M80" or "M120" beams. However, the results of intercomparisons between these labs at the M80 beam quality shows up to a 2% difference. The AAPM is in the process of revising its criteria for accrediting laboratories calibrating diagnostic instruments. They are recommending that laboratories have beams fitting on the NIST families of Half Value Layer and Homogeneity Coefficient versus kilovoltage at the 80 and 120 kVp points. The existing discrepancy between inter-comparisons is comparable to the proposed accreditation criteria. The discrepancy results from (1) a lack of NIST standard beams so that constant potential and three phase x-ray generators can match the NIST beams, and (2) different methods of defining the beam quality for the "M80" beam.

Detailed Program Characteristics

NIST already has the necessary equipment to establish these beams, namely a free-air chamber capable of operating in the appropriate energy range and a constant potential x-ray generator that can be set to the desired voltages. The major effort is to use the NIST families for the M series of x-ray beams to determine the appropriate HVL and HC. Once these are determined, it will be necessary to construct appropriate added filters (only aluminum if possible to best mimic the case in the real world where x-ray manufacturers use aluminum as the added filtration). After the filters are decided upon, it will be necessary to verify the HVL and HC and offer the service. Once NIST offers the service, laboratories calibrating diagnostic x-ray instruments will need to establish comparable beams in their facilities. A proficiency test with a NIST selected and calibrated transfer standard can then be used to demonstrate the required traceability to these new national standards.

Facilities, Staffing

Since NIST already has the equipment and personnel, the main effort of this MPD will be to devote sufficient staffing to complete the project. The effort is estimated to take no more than 0.25 person-years. The cost would be the NIST cost for a quarter of a FTE.

MPD A.6: NATIONAL AIR KERMA STRENGTH STANDARDS FOR PHOTON BRACHYTHERAPY SOURCES

Program Summary

Brachytherapy as a treatment modality is increasing in use in the United States and throughout the world. The US Nuclear Regulatory Commission has estimated that there are 50,000 procedures performed annually in the US alone with brachytherapy sources. There are a number of new sources being introduced for this purpose, some using radionuclides already on the market, but with different encapsulation or methods of construction, either of which effects the radiation output. This has especially become evident for the radionuclide ^{125}I, which presently has two forms, as well as new forms that have not as yet been introduced into the market place. Measurements have indicated that there is a 6% difference in the dose rate per unit air-kerma strength between the two current forms of ^{125}I. Thus, careful determinations of air-kerma strength need to be made with well-established standards for each new radionuclide / geometry combination to be introduced for brachytherapy.

The American Association of Physicists in Medicine Task Group 43 has issued a report that indicates that the calibration quantity of choice in air-kerma strength ($Gy\text{-}m^2 / h$) as opposed to activity. This is the preferred quantity because there are variations in the dose rate per unit activity even for the same radionuclide, e.g. ^{125}I Model 6711 and 6702 seeds that have different internal geometries. There are a number of new brachytherapy sources that are appearing in the market place, especially for the treatment of prostate cancer. At present, there are no air-kerma strength standards for these sources, although they are being widely used in clinical practice. This lack is particularly urgent for those seeds being used in clinical trials. In addition, there is presently only an interim standard for the measurement of air-kerma strength for high dose rate ^{192}Ir brachytherapy that would be important to establish through some basic principles. Thus the goal of this measurement program would be to establish air-kerma strength, and if possible, absorbed-dose rate standards at the National level for not only presently available brachytherapy sources, but for any future sources as they become available.

Detailed Program Characteristics

NIST currently only offers a calibration service for ^{125}I brachytherapy sources. There are indications that there is currently an error in the NIST reentrant ionization chamber calibration method which necessitates that output air-kerma strength needs to be altered by 10%. This leaves the medical physicist, who has to measure these seeds, in a quandary as to what is the correct value to use in treatment planning. In addition, there are other sources, e.g. ^{103}Pd, for which there is no traceable calibration to national standards. It has become evident that the manufacturer's activity value cannot be relied

A.6.1¾ Wide Angle Free Air Ionization Chamber (WAFAC) used to establish the photon air kerma strength for seeds of iodine-125 and palladium-103.

upon to any better than about ±10%, and that the manufacturers have no basis on which to provide such calibrations other than some perfunctory chemical analysis.

NIST has developed a Wide-Angle Free-Air Chamber (WAFAC), see Figure 6.1, which can be readily used as a national standard for the calibration of photon sources of 30 keV and below. NIST needs to more fully characterize this standard, and introduce it into routine use for calibrations. They need to obtain sources for such characterizations and to develop methodology for any new sources that may be introduced in the future for brachytherapy.

A.6.2¾ Radioactive seeds used in prostate cancer therapy.

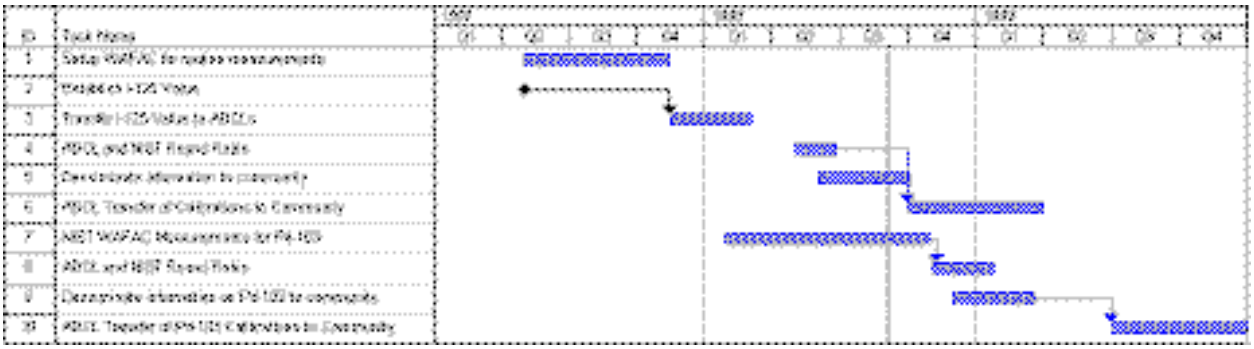
A national standard needs to be established for the calibration of ^{192}Ir sources. The interim standard at the University of Wisconsin using an interpolated calibration factor needs to be tested and refined at NIST. If applicable, it needs to be extended to other photon energies between 30 keV and 600 keV for any other brachytherapy sources which may appear in this energy range. Once the ADCLs have established their calibration capabilities, NIST needs to develop a transfer standard for use in proficiency testing the ADCLs to verify their demonstrated traceability to the national standard.

The long-range goal of this project should be the development of an absorbed-dose rate standard for photon brachytherapy sources. This standard would provide the needed quantity as a function of position about the source in three dimensions.

Facilities, Staffing

Standards need to be established at NIST that can then be transferred to the medical physics community. This is more of a challenge than the situation of a bare radionuclide, since most medical applications involve the insertion of the source in some type of holder. There are differences in source encapsulation and in substrates used, or in the method of deposition of the radionuclide, all of which effect the radiation output. NIST needs to develop methodology to characterize the effect of these differences, and set a standard for the radionuclide / geometry. In the short term, this will probably be the WAFAC for low energy radionuclides, and the interpolated calibration factor method for higher energy sources. In turn, this calibration will be transferred to the ADCLs which will then transfer it to the medical physics community.

As this report is being published, the AAPM has written a recommendation that any new radionuclide, or any variation of a presently-used radionuclide, needs to fulfill two major criteria before it is marketed to the general medical community (AAPM, One Ellipse Plaza, College Park, MD). These criteria are: (1) a NIST calibration of the particular configuration of the new brachytherapy source, and (2) two independent determinations and publication of AAPM TG#43 parameters.



A.6.3 – Roadmap for photon brachytherapy.

MPD A.7: STANDARDIZED DOSIMETRY FOR INTRAVASCULAR BRACHYTHERAPY SOURCES

Program Summary

Coronary artery disease is the leading cause of morbidity and mortality in the western world. Approximately 400,000 angioplasties are performed annually in the USA. Although major complications from balloon angioplasty occur in only 1-2% of the patients, restenosis occurs in 35-40% of the patients and hence is a major limitation to angioplasty. Coronary stent placement in conjunction with angioplasty can reduce restenosis rate to 22-32%. Recent preclinical studies indicate that doses in the range of 10 to 30 Gy may reduce substantially restenosis in patients who have undergone a balloon angioplasty. Using intravascular brachytherapy, radiation doses in this range can be delivered with minimal normal tissue toxicity, because of the localization of dose to the immediate vicinity of radioactive sources. It is estimated that the restenosis rate may drop from roughly 35-40% to well below 10% if radiation is delivered to the obstruction site during or after angioplasty. The cost of restenosis has been estimated to be $4000 to $7000 in direct costs for the first episode of restenosis. The societal cost of restenosis in the United State of America is estimated between 800 million and 2 billion dollars per year. Therefore, the potential of intravascular brachytherapy in reducing restenosis has aroused a tremendous interest in the radiation oncology and cardiology communities.

Dosimetry at distances of the order of a millimeter is poorly known. In traditional brachytherapy the dose is typically specified at 1 cm from the source and effects of low energy photons and secondary electrons are essentially ignored. In the intravascular brachytherapy, however, the entire lesion may be 1-3 mm in thickness. To understand the results of various preclinical studies using a variety of radionuclides and delivery systems, it is essential to determine the dosimetry in the millimeter range. A better understanding of dosimetry in the millimeter range will help in the development of optimum clinical devices and their efficacious use in different institutions using different radionuclides and devices.

Improved accuracy in dosimetry will allow the use of multiple radionuclides in a variety of devices that may have their own unique advantages, in multiple institutions. In other words, accurate dosimetry and a common dose specification is essential for a meaningful evaluation of various biological and clinical studies.

Detailed Program Characteristics

The major goal of this MPD is to be able to accurately calibrate intravascular brachytherapy sources at mm distances for the various types used in this modality. The types of radiation sources and their geometries are rapidly evolving for this modality so a

detailed program cannot be presented. The following items, however, would be part of the base program for this MPD.

1. NIST

- Develop the capability for calibrating gamma and beta intravascular brachytherapy sources.
- Develop the capability for calibrating sources for the various geometries used:

  –point (e.g., HDR ^{192}Ir source)

  –line (e.g., ^{90}Y wire source or ^{90}Sr seed train)

  –area (e.g., ^{32}P radioactive stent)

  –volume (e.g., ^{188}Re-solution filled balloon)
- Develop standard geometry for source calibrations
- Develop transfer standards for selected sources
- Develop proficiency testing procedures

2. ADCLs

- Develop in-house standards
- Develop standard calibration procedures
- Develop appropriate quality control procedures
- Pass proficiency test
- Become accredited for this service

3. USER

- Obtain calibrated in-house standards for types of brachytherapy sources used at their facility
- Develop calibration methods for actual sources used before patient treatment
- Develop quality control procedures

Facilities, Staffing

Establishing the entire program of interventional brachytherapy is a complex project and beyond the scope of CIRMS. Hence this section focuses on the role of standards, measurements and calibrations used in this modality. NIST would have to develop appropriate national standards for these sources for the close distances involved. This would be a multi-year effort with a few sources per year being developed. In addition

the methodology for developing the dosimetry for both beta and gamma sources needed for these national standards needs to be fully developed and verified. It is anticipated that a full FTE would be involved for several years. At the ADCLs, it would take an FTE during the development phase and the a fraction of an FTE during the routine service phase. It is anticipated that there would be guidance for the user from professional organization on how to setup and monitor an appropriate program for calibrating intravascular brachytherapy sources before treating the patient.

B. PUBLIC / ENVIRONMENTAL RADIATION PROTECTION MPDS

RADIONUCLIDES IN THE ENVIRONMENT

Radionuclides have permeated and resided in the environment since the formation of the earth and most human radiation exposure arises predominantly from these primordial radionuclides. The environmental radioactivity fields are sufficiently low to not cause untoward health risk while providing extremely useful tracers of geochemical processes to improve understanding of the environment and mankind's impact on it. However, additional releases of anthropogenic radionuclides into the environment, in a few localized areas, have resulted in additional meaningful radiation levels with significant financial consequences and potential impact on human health. In these elevated radiation areas, it is necessary for environmental management to accurately assess the damage, develop cost-effective remediation strategies, evaluate the effectiveness of the remediation activity, and monitor the cleaned-up site into the future. Additionally, persons directly engaged in the remediation, decontamination and decommissioning efforts will have to be monitored for occupational exposure.

Environmental Management

The world currently faces several critical issues brought on by the potential redistribution of large quantities of radionuclides in atmospheric, oceanic, terrestrial, and bio-environments. Global contamination, potential for unplanned catastrophic releases, restoration of contaminated land, and decontamination and decommissioning of nuclear power plants and weapons facilities can all have large impacts on the world economy, the environment and human quality of life. The global environment has been contaminated with EBqs (10^{18}) of radioactive fallout (Bradley, 1997; Bradley et al., 1996; League of Women Voters, 1982; 1985). There is the grave potential for unplanned releases from wastes in oceans and on land from reprocessing and storage facilities containing TBqs (10^{12}) of radionuclides:

- PBqs (10^{15}) of radioactive waste in degenerating ocean-based storage,
- Tens of thousands cubic meters of high-level spent fuel in temporary storage at nuclear power plants,
- Hundreds of thousands cubic meters of transuranics (TRU) in temporary storage,

- Hundreds of thousands cubic meters of High-Level waste in temporary storage, and
- Millions of cubic meters of low-level waste in temporary storage.

Furthermore, there is the potential of catastrophic releases and redistribution of radioactive materials into the environment that will contaminate water resources, crops, animal resources, land, air, and humans (e.g., Chernobyl). Remediation efforts must address the temporary storage of tens of thousands cubic meters of high-level spent fuel at nuclear power plants; hundreds of thousands of cubic meters of transuranic weapon fabrication and reprocessing waste; hundreds of thousands of cubic meters of high-level radioactive waste; and millions of cubic meters of low-level radioactive waste. Remediation will be required for hundreds of square kilometers of contaminated land and hundred millions of cubic meters of radioactive mill tailings. Monitoring the effect of subsurface injection of EBqs of radioactive waste and PBqs of discharge to surface waters is equally important. Additionally, 53 DOE sites and nearly 100 nuclear power reactors will be decontaminated and decommissioned at the cost of hundreds of billions of dollars (C&E News, March/April 1998) in the U.S. alone. Furthermore, tens of thousands of radiation workers will potentially face radioactivity exposure during waste handling which requires safety monitoring.

As the various government agencies better define their interactive roles in the environmental remediation and compliance activities, there has been a growing need to define programs that have multiagency consensus so that the remediation activities performed by one agency will be accepted by the other participating agencies. After several years of development, the DOE, EPA, NRC and DOD have prepared a document entitled "Multi-Agency Radiation Survey and Site Investigation Manual"(MARSIM) for release in 1998 that will address the requirements for radiological survey and site investigation activities for plant decommissioning or site remediation projects. A similar document for consensus requirements by EPA, NRC, DOE, DOD, DOC and DOI for radioanalytical services (Multi-Agency Radiochemistry Laboratory Analytical Procedures—MARLAP) related to plant decommissioning and site remediation activities is being prepared.

Addressing the broad range of environmental radionuclide issues will be dependent on innovative measurement techniques that yield accurate, precise and defendable data for decision making. The technical need is for faster (real-time), more reliable and cost effective field measurements and remediation technologies for site characterization and monitoring; radioactive waste characterization (background to hot-cell levels); waste management process control and safeguards; and personnel monitoring.

Geochemical and Geophysical Applications

The dispersion of anthropogenic and naturally occurring radionuclides throughout the environment has provided the academic and regulatory communities with extremely

useful tools to study geochemical and geophysical processes in great detail and with significant economic and human inquiry consequences. Berrylium-10 has been used to understand aspects of glaciology and climatology (climate records, helio- & geomagnetic modulation, erosion), cosmochemistry and *in situ* production (solar/cosmic-ray flux variation, meteorite exposure age, meteorite metamorphic histories), and ocean and atmospheric processes (subduction rates, sedimentation rates, bioproductivity, water column dynamics, sediment dynamics, production of mineral resources, burial dating). Similarly, ^{36}Cl as been used for studies including: solar/galactic ray variation, meteoritic model verification, lava flow & volcanic bombs, concordance at de-glaciation sites, aquifer recharge, glacial dating, soil weathering, water age, rock age, and ocean circulation. Iodine-129 has been used to investigate iodine migration in Three Mile Island sediment and for determination of rock and water age. Strontium-90 and ^{137}Cs have applications in dating soil dynamics and stratification. Carbon-14 has long been used to date organic ruminants, soil strata and archaeological relics, and define historical solar flux variations. Lead-210 has found uses in determining sedimentation rate and atmospheric circulation and residence times. The uranium-lead couple has been an important dating tool that reaches deep into terrestrial history. Meanwhile, the uranium-thorium system has been used to study particle transport in rivers and seas, magma petrogenesis and flux rates, and mineral thermochronometry.

Most of the geo-applications currently require atom-counting capabilities that have isotopic selectivity as high as 1 part in 10^{15}. The challenges for future study will be detailed evaluation of radionuclide partitioning and speciation in the environment and geochemical processes at the micro to molecular level.

Human Protection

Radiometrology investments for occupational and public protection have been focused on routine monitoring, incident management and biokinetic model validation. Recent notable health protection efforts resulted in ANSI Standard N13.30, "Performance Criteria for Radiobioassay," and the Transuranium and Uranium Registries to validate actinide *in vivo* measurements by detailed post-mortem radiochemical analysis. Incident management for emergency contamination situations now involve issues that include evaluation of low-level veteran exposure to nuclear weapon test debris and depleted uranium. Biokinetic studies have improved understanding of bone remodeling, actinide redistribution kinetics, national and international model validation, actinide histo-pathology, cancer risk coefficients, radio- and chemical-toxicity of uranium in kidneys, and transfer of actinides across the placental barrier.

Future challenges to be addressed by the low-level radiochemistry community encompasses strengthening the defensibility of measurements, the development of traceability linkage of routine *in vivo* and *in vitro* radiobioassay measurements to the national standards, and extending incident management and biokinetic evaluations with μBq sensitivity actinide isotopic metrology.

PERP Future Vision

Measurement tools for accurate assessments are fundamental to addressing the issues of radionuclides in the environment and their impact on humans. While there are many radioanalytical methods, detection systems, and calibration standards available, current metrology needs require rapid reduced-cost turn-key analytical methods and technologies with higher selectivity and sensitivity that yield defensible analyses. The development of these measurement tools, and their calibrations, will be based on pooling multi-disciplined expert teams which requires considerable resources that can be found only in national initiatives. PERP's goal is to provide a forum to identify areas of opportunity for reliable key future measurements and standards development, produce a strategic plan, and initiate funding support to meet the nation's future environmental and bioassay radionuclide metrology needs. PERP will focus its attentions on three general metrology areas: (a) analytical methods and Standard Reference Materials; (b) instrument development; and (c) measurement assurance programs.

Analytical Methods and Standard Reference Materials: The enormous environmental and human safety issues have such profound national implications, and the measurement problems are so challenging, that it is essential that PERP examine and coordinate solutions to some of the field and laboratory measurement problems that involve, particularly, the validation of radiochemical dissolution and separation, radiospeciation and radioanalytical methodologies. This will entail the use of primary and secondary radioactive sources in the form of standard point sources of alpha, beta and gamma rays as well as large-area sources, matrix radioactive standards and ultra-low level tracers. These Standard Reference Materials would be instrumental in also establishing derived QC reference materials for site-specific remediation projects, including the traceability of TRU waste measurements before shipment to the Waste Isolation Pilot Plant (WIPP) site. Such sources are essential when contractors and regulators must declare when a remediation and removal program have been completed.

Instruments: There are many needs for a new generation of instrumentation which can provide survey and quantitative real-time field measurements, radionuclide and stable element measurements for high-level waste process control, and high selectivity and sensitivity measurements of actinide and long-lived pure beta radionuclide isotopic composition. In support of environmental monitoring, bioassay and Standard Reference Material development and certification, the development of fairly inexpensive yet highly reliable, turn-key ultra-selective and sensitive methods (such as atom-counting by glow-discharge resonance ionization mass spectrometry, inductively-coupled plasma mass spectrometry, and thermal ionization mass spectrometry) is crucial.

Measurement Assurance Programs: As agencies accept each other's programs and coordinate their activities, there will be a need to demonstrate the quality of analytical data in support of the cleanup efforts by the different agencies. PERP has a major role in coordinating the establishment of a national measurement assurance or traceability program wherein the measurement assurance programs for the various agencies can

obtain measurement traceability to the national physical standards. The basis and outline for such a program have been described in the recently issued ANSI Standards N42.23 and N42.22. With all agencies, or their contractors, participating in the program, the interagency acceptance of analytical results based on a comparable performance would be ensured. This is especially important for those programs or agencies having a performance-based philosophy rather than a method compliance philosophy for laboratory analytical services.

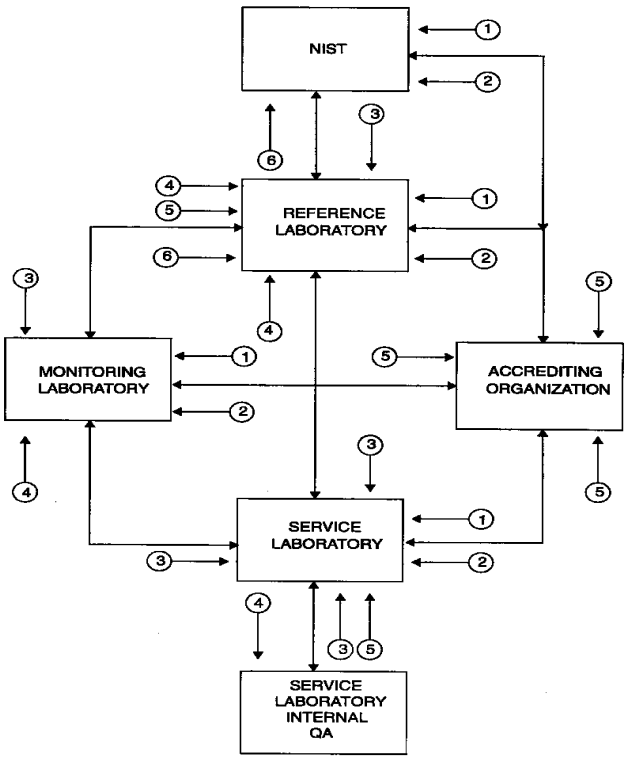
Based on the measurement and standards needs described above, PERP has identified the following MPDs as the highest priority action items:

- B.1 Traceability to NIST (new MPD)
- B.2 Field Survey Instruments and Calibration Standards
- B.3 Radioactivity Standards for Waste Cleanup and Site Remediation
- B.4 Atom-Counting Measurement Techniques for Environmental Monitoring and Bioassay
- B.5 Speciation of Radioactive Elements in Contaminated Soils and Sediments (new MPD)

MPD B.1: TRACEABILITY TO NIST FOR REFERENCE, MONITORING AND SERVICE LABORATORIES

Program Summary

The term "traceability" has become a complex concept having subtle differences in meaning depending on the specific application and the organization effected. Recently, as an result of the ANSI process, a national standard has been developed that clarifies the process of how to become traceable to NIST. Published in 1996, the new standard ANSI N42.22–1995, entitled "Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control," was primarily developed to address the needs of the commercial radioactive source manufacturers related to NIST traceability for the materials that they manufacturer, produce or sell. However, the guidance and concepts provided within the standard are applicable to any organization preparing radioactive materials that desires to be traceable to NIST.



B.1.1¾Conceptual diagram of the national performance testing program for measurements and associated instrumentation quality assurance (ANSI N42.23).

ANSI N42.23-1996 was developed to address a national concern to establish a national measurement assurance program for the radioassay laboratory community, especially for the environmental and bioassay applications. This standard, entitled "Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories," was published in 1997 after nearly ten years of preparation. The purpose of the standard was to provide the basis for the creation of a national measurement quality assurance (MQA) program(s) that will optimize the quality of radioassays performed by service laboratories in the United States. Within the framework of the national MQA program description is the delineation of the responsibilities and interaction of NIST, the accrediting organization and the reference, monitoring and service laboratories.

Currently, there are two principal government national measurement programs related to environmental sample radioassay laboratories. These include the U.S. Environmental Protection Agency's Interlaboratory Comparison Program administered by the National Exposure Research Laboratory, Las Vegas, NV and the Department of Energy's Quality Assurance Program administered by the Environmental Measurement Laboratory, New York, NY. Other government MQA programs include those for *in vitro* and *in vivo* bioassay as well for the mixed analytes in a waste matrix (MAPEP) administered by DOE's Radiological and Environmental Sciences Laboratory (RESL). In addition, RESL provides a nuclear power plant effluent MAP service under contract to the US Nuclear Regulatory Commission. Recently, there has been a number of DOE specific measurement assurance programs (MAPs) established in support of the Sample Management Offices at the various DOE sites for the analytical data verification and validation process. Of the many long-term and recently created government and commercial MAPs, currently only the NRC's program for effluents administered by RESL is traceability to NIST. Traceability criteria for this program were established between the NRC and NIST in the 1970s.

More recently, there is a need to develop a MAP for the newly develop technologies that will transcend traditional decay emission radioassays. These technologies include the various mass spectrometry techniques and fission tract analysis for the long-lived nuclides.

During the past several years, several government agencies have collaborated on the development of multiagency consensus guidance on plant decommissioning and site remediation activities (MARSSIM and MARLAP). With shrinking government funds, it has become very cost-effective to share resources and to accept analytical data derived under consensus documents. As such, the case for a national MAP as one element to assure quality analytical data becomes more viable to all parties. Even though ANSI N42.23 provides generic guidance, there is a need to delineate and define various technical and program elements for traceability to NIST for environmental radioassays and radiobioassays.

Detailed Program Characteristics

Initially, a steering committee comprised of NIST and government and commercial laboratory stakeholders should be established. If desirable, individual organizations could establish their own NIST agreed upon traceability criteria to meet their program needs. The steering committee would develop a document that will address the implementation of ANSI guidance documents N42.23, N42.22 and possibly N13.30 as they

B.1.2 Radiochemists in low-level radioactivity laboratory.

relate to traceability to NIST. The steering committee should focus on the development of:

- recommendations relative to the program elements of a national MAP and the working relationship between NIST, reference, monitoring and service laboratories and the accrediting agency,
- a "needs" MAP sample matrix in terms of radionuclides, media type and analyte concentration level,
- traceability criteria,
- data quality objectives for the preparation and distribution of performance evaluation samples,
- sample preparation procedure validation criteria applicable to all matrices and analyte concentrations,
- sample preparation verification criteria applicable to all matrices and analyte concentrations,
- testing requirements between NIST, reference, monitoring and service laboratories,
- a quality assurance assessment criteria for the participating laboratories,
- a selection process for choosing an administer for a national NIST Traceable MAP for environmental and bioassay media, and
- a mechanism to facilitate the equitable funding of the national MAP.

Progress on MPD B.1 Since Publication of 1995 Need Report

This MPD was recognized as a major priority in November of 1996. Although this MPD is relatively new, numerous activities have occurred to define the program needs for this national endeavor. First of all, NIST traceability for the commercial source manufacturers was defined within ANSI N42.22-1995 as published in 1996. In 1996 and 1997, Dan Montgomery made numerous presentations to the national and international technical community relative to the content of the standard. The ANSI standard defined a statistically-based NIST traceability criterion that incorporated the measurement uncertainties of both NIST and the source manufacturer.

The ANSI standard N42.23 entitled "Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories" was published the second quarter of 1997. NIST hosted several meetings with government, commercial and industry representatives to discuss a NIST program that will facilitate NIST in providing traceability to a number of organizations and laboratories according to the various program drivers and needed traceability criteria, such as ANSI N42.22 or the NRC/RESL - NIST traceability program. The national program is being called the "NIST Radiochemistry Intercomparison Program" or NRIP. The NRIP will provide the performance evaluation program for the reference and monitoring laboratories under the ANSI N42.23 framework.

MPD B.2: CALIBRATION STANDARDS FOR FIELD SURVEY INSTRUMENTS AND ENVIRONMENTAL DOSIMETRY

Due to the similar program elements and needs, the MPD B.4 entitled "Capabilities of Field Radiation Survey Instruments for Decommissioning," has been combined with the MPD B.6, Calibration and Transfer Standards for Environmental Dosimetry and a new MPD defined.

Program Summary

In 1997, the NRC published regulatory requirements and regulatory guidance relative to the specific radiological criteria for the decommissioning of lands and structures. The criteria would apply to the decommissioning of most types of facilities licensed by the NRC and the Agreement States. If adopted in final form, these criteria would be applied to determine the adequacy of remediation of residual radioactivity at NRC-licensed facilities.

Certain proposed radionuclide limits approach levels found naturally in the environment that could pose technical challenges for determining compliance using existing radiological survey methods. In 1995, guidance documents were written by the NRC (eg., NUREG-1907) on the proper calibration of a variety of field survey instruments that are typically used in decommissioning activities. However, for measurement and analysis of residual radioactivity at or near background concentrations, alternative radiological survey methods may be required to demonstrate that a site or facility has achieved appropriate decontamination levels. This will likely entail the application of nuclide-specific measurements for increased detection sensitivity, such as *in situ* spectrometric survey techniques. Although such techniques are more sophisticated than current radiological survey practice, their use may lead to a decrease in overall survey costs for certain sites and facilities.

Thermoluminescent dosimeters are typically used as passive devices for the direct measurement of gamma radiation being emitted from cosmic, terrestrial, and man-made sources in areas where the general public has unrestricted access with respect to radiation control. A secondary measurement method, field instrumentation, should be used for development and testing of the dosimeters to verify exposure fields to which the dosimeters are subjected. Both environmental dosimeters and field instrumentation, including *in situ* gamma spectrometry are calibrated incorporating high-level, high-energy gamma-ray ^{137}Cs and ^{60}Co sources, even though low-fluence low energy gamma-rays are encountered in the actual environment. Technology and quality assurance programs need to be developed for use in the calibration of field instrumentation for low-level varied-energy gamma fields.

Detailed Program Characteristics

The minimum detectable limits (MDL) and response of a variety of *in situ* monitoring instruments (e.g., total alpha, beta, gamma, total exposure rate and field gamma spectrometry) that have been identified in various documents should be verified using reference materials or a reference field area certified for radiation quality and exposure rate by NIST. This is important, especially for regulatory purposes because the MDL establishes an activity level at which the cost of assays starts increasing rapidly. Acceptable levels of radioactivity at restoration sites would be partially determined by these values.

Needed standards are:

- wide area, to test *in situ* monitoring instruments and
- bore hole standards for fixed and moving instruments

Again, intercomparisons and QA efforts among the DOE laboratories, NRC contractors and selected other organizations are critically needed.

For environmental TLDs, this program will bring unity of measurement capabilities to existing environmental dosimetry programs located at nuclear facilities, laboratories, and testing programs such as the International Intercomparison of Environmental Dosimeters series and other environmental intercomparisons performed by the Commission of the European Communities (CEC) and other agencies. The National Institute of Standards and Technology (NIST) is initiating its program to develop standard low-fluence gamma fields and to develop a quality assurance program which will include standard transfer instrumentation, a low-background low-scatter facility, and an environmental chamber: the Environmental Measurements Laboratory (EML) is moving ahead with field instrumentation development and characterization of low level fields and is preparing to initiate the pilot testing in preparation for ANSI N13.29 Environmental Dosimetry Performance—Criteria for Testing (draft). Instrumentation needed to carry out the plan includes semi-conductor / diode gamma-ray detection equipment and recording pressurized ionization chambers. TLD or other materials suitable for environmental dosimetry will be required to compare results as they would be incorporated in the field. Technology to measure low-fluence gamma fields and x-ray fields for the instrumentation and dosimetry will need development. Procedures for the preparation of low-fluence gamma fields, for assessing measurement capabilities of dosimeters and instrumentation in low-fluence gamma fields over a range of energies and under varied environmental conditions, and for the calibration of dosimeters and instrumentation will, need to be developed and standardized.

Progress on MPD B.2 Since Publication of 1995 Needs Report

Progress has been made in two principal areas of this MPD: *in situ* gamma-ray spectrometry for environmental remediation, and performance testing of environmental dosimeters. First there was a workshop conducted at Brookhaven National Laboratory in September 1997 that was sponsored by the Environmental Measurements Laboratory of DOE. Six technical specialists from government, industry and commercial manufacturers participated in the two-day workshop. Evaluations were conducted at two field test plots of state-of-the-art gamma-ray spectrometry systems and computer modeling codes for each participant's equipment. One site had medium levels (10 pCi/kg) of ^{137}Cs uniformly distributed as near-surface contamination. The other site was considered a low-level agricultural site and contained only naturally-occurring radionuclides as well as the long-lived residual weapons testing radionuclides. The results of the measurements were compiled, intercompared and discussed. The ANSI Draft N13.29 Performance Testing of Environmental Dosimeters is currently being pilot tested by the Environmental Measurements Laboratory of the DOE. The testing criteria are applicable for environmental dosimeters, notably TLDs, related to facility monitoring, interim remediation, restoration projects, waste sites and fence-line monitoring.

MPD B.3: RADIOACTIVITY STANDARDS FOR WASTE MANAGEMENT AND SITE REMEDIATION

Program Summary

The stakeholders involved in the first MPD on traceability to NIST will be the drivers for the program needs of this MPD. In addition, this MPD should be considered as a dynamic needs document wherein the needs will change according to the progress made and information gathered during waste cleanup and site remediation activities.

Radioactivity measurements that support environmental restoration must be credible to withstand stakeholder and public scrutiny. To fulfill this goal, analytical methodology should be validated. Intercomparisons of environmental radioactivity measurements have shown discrepancies even between the most prestigious laboratories. Measurement instruments should be calibrated with appropriate standards and reference materials to provide traceability to the national radioactivity standards. This is important for compliance with regulatory guides, written standards, and other QA requirements. Furthermore, to provide independent assessments; reference, secondary, or QA laboratory operations should periodically be evaluated against programmatic objective criteria by third-party technical experts.

In addition to the provision of standard liquid SRMs for instrumentation calibration, QC intercomparison programs and procedure validation mentioned above, additional special matrix standards will be necessary for the waste management and site remediation projects throughout the country. The performance requirements for performing chemical and radiological analyses for environmental and waste management programs are varied. For radionuclide analyses they fall into three levels:

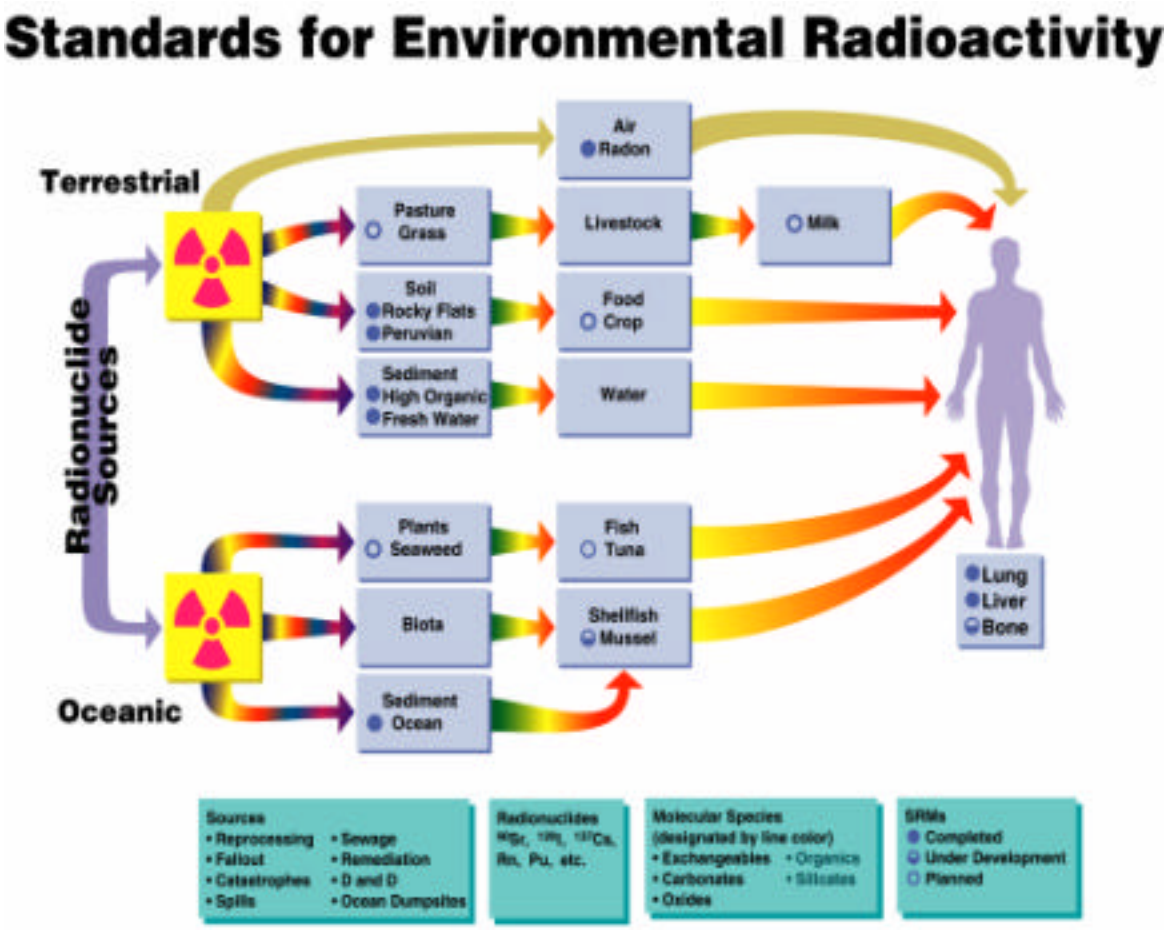
- environmental levels for perimeter environmental monitoring,
- relatively high levels for characterization of radioactive waste drums,
- an intermediate level for environmental restoration.

The current supply of environmental-level soil Standard Reference Materials (SRMs), primarily from NIST, EML, and the IAEA, is adequate for the environmental monitoring and some of the environmental restoration work. However, new SRMs are needed that are specific to the types of radiochemical analyses, such as direct counting and for digestion prior to counting. SRMs developed for direct counting may not be adequate for uses where the sample is either totally or partially digested and purified before counting. In addition, SRMs based upon soil types found in the eastern part of the U.S. are not applicable to the southwest. The best type of reference materials for work associated with specific sites is site-specific materials. These materials can be used as double blind quality control samples since they will resemble the actual samples more closely. Also, few, if any, reference materials are available for the DOE waste form types. Water

standard needs are similar to the soil standard needs. *Spiked matrix* standards are presently available to a very limited degree from DOE (EML) and INEL (DOE).

Detailed Program Characteristics

The program is divided into two major endeavors; the preparation of basic liquid standard reference materials for radionuclides needed in waste characterization / site remediation activities and the development of a matrix characterization program for those needed site specific QA or performance evaluation purposes.



B.3¾ Standards for Environmental Radioactivity.

Calibration Standards for Common Matrices, Tracer and QC Intercomparison

Primary radionuclides standards are required for waste characterization for WIPP and other DOE waste programs. In particular, the standards needed for low-level perimeter environmental monitoring are:

- low-energy or long-lived (exotic) radionuclides as yet uncharacterized in waste storage tanks, e.g., ^{41}Ca, ^{53}Mn, ^{60}Fe, ^{59}Ni, ^{63}Ni, ^{79}Se, ^{93}Zr, ^{94}Nb, ^{93}Mo, ^{99}Tc, ^{107}Pd, ^{113}Cd, ^{126}Sn, ^{129}I, ^{135}Cs, ^{151}Sm, ^{231}Pa,

- tracer materials (yield monitors) such as $^{236, 242}$Pu and ^{243}Am, and
- an air filter standard with radioactivity containing dust particulate on the surface. Simulated radon progeny interferences should also be placed on the filter.

These materials will be used for procedure validation/instrument calibration, tracer recoveries and for internal QC and national measurement assurance programs. Ongoing internal QC programs, site specific interlaboratory PE programs for contract service laboratories and newly developed MAP programs can use these materials as needed. An important goal of some intercomparisons would be the assessment of techniques and analytical procedures. A primary goal should be the use of the materials in national MAPS to ensure traceability to NIST. Intercomparisons and the use of the NIST natural matrix standards used as blinds could be used to initiate this activity. Following the development of complex site specific matrices having the radionuclide of interest, these materials can be distributed for procedure validation purposes.

Site Specific Radioactive Soil Matrices

The INEL and ORNL Sample Management Offices have projects for the preparation of site-specific soil performance evaluation (PE) samples. At the INEL, these PE soil samples are being prepared using residual samples that were collected from the Warm Waste Pond and Retention Basin areas of the Test Reactor Area as the source materials. The residual samples are combined, blended and fortified (if necessary) or diluted if necessary prior to being aliquoted into new containers. The homogeneity of the materials are checked and then the materials characterized according to requirements specified in EGG-ER-10720 (in draft form) quality assurance project plan. Specifics for the preparation of the materials and the homogeneity check have been outlined. A similar, but less sophisticated program for site specific performance evaluation materials, is currently being developed for ORNL . The goals of these programs are to:

- create site-specific QC soil materials for use with radionuclide and metals analyses,
- provide a source of soil QC samples containing analyses at expected environmental concentration levels,
- create a tool to assist radiochemical laboratories in maximizing their method performance at low levels,
- provide a soil QC tool to analytical laboratories for real-time QC management,
- provide an inventory of soil PE samples for either periodic or real-time assessment of laboratory performance through the use of various types of INEL indigenous diluent soils, and

- provide true double blind site specific reference materials that will be used by the DOE Sample Management Offices in the conduct of QC programs related to the commercial contract laboratories providing radioassay services.

Natural matrix standards (NMS) will require a commitment by NIST to certify low-level radioactive materials of various matrices. This need may require NIST to initiate developments in radiochemistry, mass spectrometry, radiometrology and to evaluate current material certification protocols. In some cases, the certification process may require the assistance of the premier (secondary) laboratories in the country in order to gain consensus values. These laboratories should be traceable to NIST as reference or monitoring laboratories as recommended in ANSI N42.23 and the MPD B.1 Traceability to NIST. Under ANSI N42.23 guidance, the reference and monitoring laboratories will generate and certify the majority of the site-specific PE materials. However, NIST will certify materials sent to them or will indirectly certify site specific PE material prepared at a traceable reference or monitoring laboratory.

Materials should be carefully selected for the certification process so that a range of possible constituents within the matrices are included. Once certification of the materials has been established, a small suite of such standards that would cover the range of possible radiochemical problems. Since there are many sites to be tested, which differ radically from the other in radiochemical challenges, use of the materials at other sites would be discouraged except to test the robustness of the analytical technique.

Action Items

Action items include the following:

- conduct a workshop to discuss production / characterization methods for performance evaluation materials,
- publish proceedings of the workshop, with emphasis on a recommended protocol for the preparation of PE materials, and
- develop a short list of site specific matrices that provides a range of analytical challenges.

Progress on MPD B.3 Since Publication of 1995 Needs Report

Some progress was made in the application of site specific soil and water matrices in the measurement assurance programs conducted by the Sample Management Office at DOE sites. In 1996 Jacobs Engineering, under contract to the Oak Ridge DOE Sample Management Office, began a double blind MAP wherein soil and ground waters taken from the Oak Ridge National Laboratory reservation were enhanced with select radionuclides and metals germane to their analytical programs. The radionuclide concentrations were established at three to five times the required detection limits specified within the contracts established with various commercial laboratories. Typical radionuclides included in the matrices have been the inherent naturally occurring radionuclides and the added nuclides of ^{226,228}Ra, ^{232}Th, ^{239}Pu, ^{99}Tc, ^{90}Sr, ^{60}Co, ^{137}Cs and the U isotopes. Verification of the radionuclide concentrations of the prepared materials has been performed by a NIST traceable laboratory, i.e., one that participates in the NEI/NIST traceability program. The prepared materials are included in the batches of routine field samples forwarded to the various contract laboratories providing analytical services to the Oak Ridge DOE office. The performance of the commercial laboratories has been evaluated using a quasi statistically-based acceptance criteria.

The Sample Management Office of DOE–Idaho has used site specific soil samples containing various radionuclides for several years. These materials have been dried and pulverized to a very tight particle size distribution to ensure homogeneity. Variations in concentration levels were achieved through the blending of the contaminated and non-contaminated site specific soil materials having similar particle size and density. More recently, the staff of the Radiological and Environmental Sciences Laboratory (RESL) at Idaho Falls has produced some soils enhanced with spiked difficult-to-measure radionuclides and then blended. The materials used in the development of the performance evaluation samples, as well as the final performance evaluation matrix itself, are characterized by RESL staff. The PE materials are linked to NIST through RESL's traceability program with NIST for their measurement process, a special NIST traceability program established in the 1970s.

MPD B.4: ATOM-COUNTING MEASUREMENT TECHNIQUES FOR ENVIRONMENTAL MONITORING

Program Summary

Certain radiochemical analyses, especially for the long-lived alpha emitters, can be laborious and costly. With the expectation that cleanup and site remediation programs related to the defense program will require millions of assays over a period of 30 or more years, costing many billions of dollars, a need exists for reducing the cost of the program by developing techniques that (i) use atom counting to reduce time spent by factors of 10 per assay and (ii) perform measurements *in situ* if possible, thus avoiding laboratory analyses.

In addition to environmental sample analyses for the long-lived nuclides, current studies have shown that atom counting is very applicable for radiobioassay for certain radionuclides. Most recently, the Brookhaven National Laboratory has demonstrated that ^{239}Pu in urine samples can be measured accurately down to the 100 aCi/L level. The technique combines the isolation, concentration and purification steps of qualitative and quantitative chemistry in conjunction with inductively coupled plasma mass spectrometry. Similar mass spectrometric techniques have been developed by the Los Alamos National Laboratory, the Lawrence Livermore National Laboratory and the Battelle National Laboratory. The application of atom counting to bioassay will produce cost savings and will enable health physicist to document internal uptakes orders of magnitude than current levels.

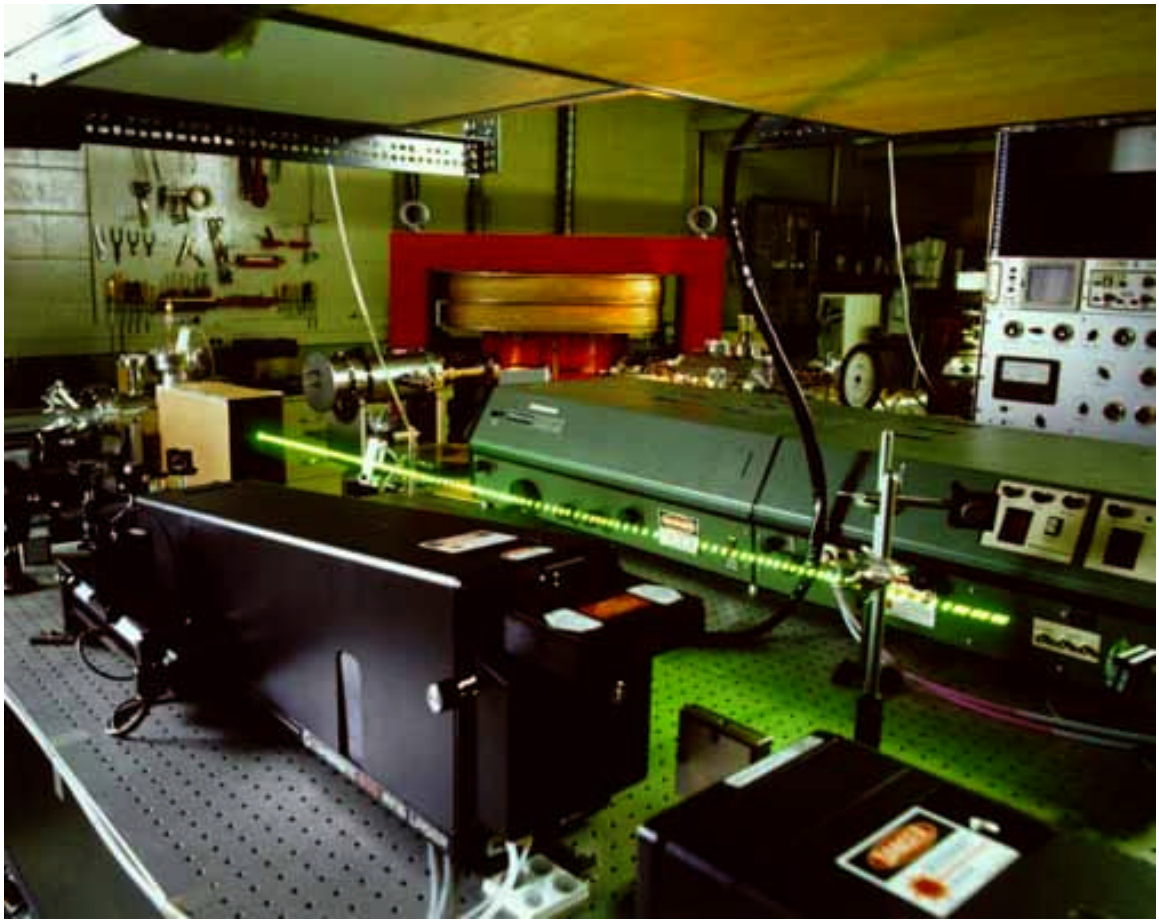
New atom counting, neutron interrogation, and radiochemical techniques including calorimetry and a pulse recording instrument for coincidence measurements will be developed. These will provide new technology and reference materials for the assay of environmental radioactivity. Critical support will be provided for a fast growing industry associated with waste clean-up and site remediation by developing new techniques for *in situ* measurement of environmental radioactivity.

The potential impact is enormous. A proposed atom counting technique could lead for the first time to direct compositional analysis of environmental radioactivity *without* radiochemistry. It could lead to a dramatic reduction in costs and improvements in accuracy of environmental radioassays. This proposal could also lead to an order-of-magnitude improvement in sensitivity of *in situ* measurements of environmental radioactivity.

Detailed Program Characteristics

An atom counting technique aims to incorporate environmental materials into a Resonance Ionization Mass Spectrometry system which has sensitivities in the PPT range or

better. This will require development of a source that can generate neutral atoms with appropriate beam intensity, width, and other characteristics. Recently a "proof-of-principle" experiment performed at NIST demonstrated for the first time that a Glow Discharge source with external laser interrogation and selection is possible. This would be the basis for the first investigations; development of procedures will present the environmental material of interest in a suitably compacted form that can be accepted by the ion source. A further aim is to develop speedy exchanges of sources for quicker turnaround times; development of a c.w. laser system for selective ionization of the neutral beam. The sensitivity is limited at present by the low duty cycle (~10^{-6}) of pulsed lasers. If diode lasers (cw) can be adapted to the RIMS problem, the sensitivity should increase dramatically. Preliminary measurements at NIST have supported the eventual feasibility of the atom counting of environmental materials.



B.4¾ Resonance ionization mass spectrometry (RIMS) system at the National Institute of Standards and Technology.

Progress on MPD B.4 Since Publication of 1995 Needs Report

A joint meeting of the D19.04 Subcommittee on Radioactivity in Water and C 26.05 Subcommittee on Plasma Spectroscopy was conducted in January, 1997 to discuss common applications, needs recognition, status of standard development and possible needed transitions between radiochemistry and mass spectrometry applications. In particular, the status of standards related the long-lived nuclides of Pu, ^{99}Tc and ^{129}I was discussed. ASTM standard C 1310-95 for the application of ICP-MS for ^{99}Tc, ^{230}Th and ^{234}U in soils after dissolution was successfully balloted and became available to the technical community. Currently, a standard developed for the analysis of ^{235,238}U in urine to support radiobioassay programs is currently in the ASTM balloting process.

Other recently published ICP-MS methods include those for

- ^{226}Ra in soils and water related to uranium mining and milling remediation efforts in Texas
- ^{237}Np, ^{232}Th, ^{235}U and ^{238}U for urine bioassay developed at the Lawrence Liver more National Laboratory
- ^{237}Np in oily waste developed at the Oak Ridge National Laboratory
- ^{99}Tc in urine bioassay developed at the Oak Ridge National Laboratory
- uranium isotopic abundances in groundwater and drinking water developed by Department of Energy—Methods Compendium.

Several national laboratories are using mass spectrometric techniques to evaluate 239Pu in urine specimens as part of their bioassay programs for occupational workers and discrete populations related to previous weapon testing activities. The Los Alamos National Laboratory, as part of their ongoing MAP for environmental and bioassay samples radioassays, maintains an active program to evaluate the performance of the thermal ionization mass spectrometer (TIMS) application for the assay of ^{239}Pu in urine specimens collected from the occupational workers at the lab site. Similarly, during the past three years, the Brookhaven National Laboratory has successfully applied ICP-MS to the assay of ^{239}Pu in urine specimens collected from the Marshall Island residents.

During 1997, a study sponsored by the Department of Energy, was conducted by NIST and the Yankee Atomic Environmental Laboratory to evaluate the capability of various mass spectrometric techniques for the assay of ^{239}Pu in synthetic urine specimens. The results of the study indicated that mass spectrometric techniques for bioassay purposes can be reliable and cost effective. In addition, ICP-MS was found to extremely sensitive and capable of detecting ^{239}Pu in urine specimens at the 100 aCi/L range in a reliable and accurate manner.

MPD B.5: SPECIATION OF RADIOACTIVE ELEMENTS IN CONTAMINATED SOILS AND SEDIMENTS

Program Summary

Extensive areas of soils and sediments within DOE sites have been documented as having significant radioactive contamination. Within current budgetary constraints, there are far more radiologically-contaminated sites at former nuclear weapons facilities than we can deal with effectively, and on a reasonable time scale. Therefore, there is a need to prioritize these sites and some hard decisions will have to be made. On what basis should policy makers prioritize the cleanup of these sites?

Although many considerations would necessarily be involved in such decisions, the "environmental availability" of the relevant contaminating species is surely a critical issue. Clearly, there is a more pressing need to remediate sites where radioactive ions may be in more mobile forms than sites where the contaminants are known to be firmly fixed in the soil matrix. Recent studies have shown that the speciation of contaminating elements plays a very important role in dictating whether an ion may move into the food chain. How then does one measure environmental availability?

B.5.1¾ Soil sampling for radioactive contamination.

Unfortunately, there is no widely accepted method available for measurement of this parameter. On the other hand, numerous studies have been performed which involve use of various chemical extraction procedures for separating soil samples into several operationally-defined fractions. The interpretation of where an ion appears in such a sequential extraction scheme is often used as a surrogate for the availability or potential mobility of that element in the environment. In other words, one commonly interprets a species as "mobile" or "labile" if it is present in one of the early, less harsh, treatments in a typical sequential extraction series. On the other hand, a "refractory" label is often assigned should the analyte report to one of the later, more vigorous, treatments. Although these interpretations are somewhat qualitative in nature, the information is far more useful than simply reporting the total concentration of radioactive elements in soil samples.

The sequential extraction approach is appealing because: (1) the analytical protocols are relatively rapid and simple; and (2) the cost is reasonable. Unfortunately, there is considerable controversy about how sequential extraction results should be interpreted and which specific procedures should be applied. There is thus an important gap in our confidence to use such methods, which otherwise have great appeal, to assess the environmental availability of radioactive elements in contaminated soils and sediments. This MPD is concerned with the following two aspects of this need:

- Development of a rigorous, standard protocol for sequential extractions of radiologically-contaminated soils and sediments.
- Application of the standard protocol to produce NIST SRM's certified for radionuclide fractionation.

Detailed Program Characteristics

The use of sequential extractions to characterize the nature of radiological contamination in soil is a departure from the normal analysis style which results in the reporting of total concentration. The development of good standards, certified by fractions as well by total content, is thus necessary for verification of results and intercomparisons of different laboratory methods. This need thus overlaps, but does not duplicate, the needs expressed in CIRMS MPD B.3 Radioactivity Standards for Waste Management and Site Remediation. The work plan designed to meet the present need must be integrated with these other programs for maximum efficiency. It is important to recognize, however, that this MPD suggests that much more detailed information be obtained on relatively few benchmark standards. Another important distinction is that development of speciation standards will necessarily require development of a standard analytical protocol. Thus, the final product will consist of an approved method as well as the natural matrix speciation standards themselves.

A June 1995 workshop at NIST addressed this issue and recommended that a concerted effort be made to evaluate existing techniques and ultimately to recommend an analytical protocol that can be universally applied. To adequately investigate existing procedures will require a systematic study that will evaluate proposed extractions from several points of view. Considerations will be given to: analytical rigor, environmental information gained, reproducibility, and cost. Experiments should be designed to assess the speciation of actinide elements (U, Am, Pu), fission products (^{90}Sr, ^{137}Cs), and decay products (^{226}Ra, ^{210}Pb, ^{210}Po) in natural soils. In addition, several "indicator" stable elements (Fe, Al, Cs, Sr, Zr, C, etc.) should be included during the development stage in order to appraise more assuredly the phase(s) attacked during each extraction step.

The study envisioned would consist initially of a relatively small group of professionals (approximately 4-6 scientists in 2 laboratories) over a period of 3 years. In the second stages of the investigation, several expert personnel and facilities would be brought into the project in an interlaboratory comparison to evaluate the efficacy and reproducibility

of the recommended protocol in different laboratories. The third phase would consist of the certification of benchmark radioactivity reference materials for community use.

Progress on MPD B.5 Since Publication of 1995 Needs Report

Substantial progress has been made on this MPD through the efforts of the faculty and graduate students at Florida State University (FSU) and the Radioactivity Group at NIST. Highlights include a CIRMS/PERP Workshop: "Radionuclide Speciation in Soils and Sediments", June 13-15, 1995, and the awarding of two M.S. theses for FSU students. The results have been presented in seven archival publications and at several conferences dealing with measurement of environmental radioactivity.

B.5.2 – Roadmap for radionuclide speciation.

C. OCCUPATIONAL RADIATION PROTECTION MPDS

INTRODUCTION TO OCCUPATIONAL RADIATION PROTECTION MPDS

Radiation workers must be adequately protected to ensure the viability of nuclear and nuclear-related industries. The cumulative number of radiation workers in the nuclear industry, distributed among DOE facilities and the various and diverse licensees of the NRC or the states, is approximately 2 million. This includes workers in the medical, industrial, nuclear power, environmental, nuclear weapons, etc., industries with annual revenues of several billion dollars. Currently, there are approximately 100,000 radiation workers in the DOE. Since radiation cannot be detected by the human senses, we must have measurement tools and techniques available in order to adequately protect the worker from radiation hazards in the work environment. Planning and controlling exposures to ionizing radiation requires accurate, reliable instrumentation to establish dose rates, indicate high exposure-rate areas, and control the spread of contamination in both the workplace and the uncontrolled environment. The day-to-day control of the radiation environment, established with sophisticated portable and installed instruments, is verified by bioassay and dosimetry programs that also rely upon sophisticated instrumentation. The dosimeter and bioassay results constitute the legal record of the workers' exposures. However, measurements made with reliable instrumentation prior to entry and during work in a radiation area are essential in minimizing workers' exposures and in complying with the principle of keeping radiation exposures As Low As Reasonably Achievable (ALARA). ALARA is used throughout the industry as a guiding principle in the control of workers' radiation exposures.

Measurements consistent with accepted standards of practice, measurements that use the best available measurement technology, and measurements that are consistent with physical standards are needed to ensure the optimum use of radiation. It is important that the industry be able to show that radiation exposures are under control and well within legal requirements. This requires not only sophisticated and reliable measurements, but also measurements that are consistent and accepted by the peer and the public community. Acceptance depends on measurements that are consistent with national and international standards. Standards include both the standards of measurement performance and the physical measurement standards maintained by national bodies such as NIST.

In recent years we have seen the increasing development and availability of sophisticated instruments and dosimeters. These improvements are the result of increasing sophistication and miniaturization of electronics. However, performance evaluations and intercomparisons have shown that response characteristics are dependent on such factors as the environmental conditions, the dosimeter processor, and the quality of calibrations. Unfortunately, the reliability of measurements has not kept pace with the increasing sophistication of the measurement tools. In the case of personnel dosimeters, recognition of the deficiencies led to the establishment of an accreditation program for dosimeter processors. This program, administered by NVLAP, has measurably improved the overall performance of dosimeter processors in the U.S. A similar program called DOELAP is operated by DOE for its facilities.

The workplace is moving from the structured work environment in many facilities to more open areas as efforts move from development and production into environmental cleanup. Work in environmental cleanup requires a different mix of radiation measurements than for the typical work environment. Contamination measurements have become a larger share of the monitoring work, and dose rates are lower and must be monitored accurately at lower levels than typically encountered in previous activities.

Expansion of accreditation programs, improvement of calibration techniques and capabilities, improvement of the control or understanding of measurement techniques, and development of new measurement techniques can all result in improved measurement reliability. In turn, improved measurement reliability will assist in protecting the occupational radiation worker.

PROGRESS ON MEASUREMENT NEEDS SINCE THE PUBLICATION OF THE 1995 CIRMS REPORT

Although a considerable amount of progress has been made on occupational radiation protection measurement needs since the publication of the 1995 CIRMS report, "National Needs in Ionizing Radiation Measurements," many of the needs require continuing support. Specific measurement program descriptions, MPDs, have been modified to reflect progress to date or rewritten/combined to better represent the needs and progress made to date.

ACTIVE MEASUREMENT PROGRAM DESCRIPTIONS

The following MPDs address measurement and standards needs in occupational radiation protection:

C.1 Improvement of Neutron Personnel Monitors
C.2 Extremity Radiation Dosimetry for Personnel Monitoring
C.3 Intercomparison Transfer Standards for Neutron Source Calibrations
C.4 Improvements in *In-vivo* Radionuclide Metrology
C.9 Type Testing Program for Instruments
C.17 Improve Radiation Measurement Infrastructure for Occupational Radiation Protection
C.18 Electronic Dosimetry

MPD C.1: IMPROVEMENT OF NEUTRON PERSONNEL MONITORS

Program Summary

Neutron personnel dosimeters are designed to be worn by radiation workers to monitor the neutron dose equivalent received during their daily activities. (Dose equivalent is a measure of the adverse biological effects of radiation, including cancer induction.) Clearly, any device to measure dose equivalent should have an energy-independent dose equivalent response. Unfortunately, this is far from true for the most commonly used neutron dosimeter the "albedo" dosimeter. This dosimeter overresponds to low energy neutrons by factors of 10 to 100. Thus, in any working environment, a relatively small number of low energy neutrons can greatly inflate the reading of the dosimeter.

C.1¾ Instruments used for personnel monitoring for neutron exposure.

There are two solutions to this problem. The first, obviously, is to design a better dosimeter. This has been a long-standing effort at many laboratories. The requirements are very severe: in addition to having a very particular response as a function of energy (covering seven to eight decades of neutron energy!), a dosimeter must have high sensitivity, be inexpensive and easily processed, since any major installation may have thousands of people "badged." Further work along these lines should continue to be encouraged.

The second solution, which has also been used for a number of years, involves careful measurement of the neutron spectrum in the particular workplace, and use of a well-characterized dosimeter so that accurate calibration factors can be developed. This approach suffers from requiring many very careful, difficult, neutron spectrum measurements. On the other hand, it can be employed using existing technology.

Present calibration technology focuses on the use of moderated and unmoderated Cf-252; the moderated Cf-252 was selected to be a good simulation of the spectra occurring in reactor environments. Unfortunately this leaves large uncertainties in high energy

neutron fields (accelerators) and around low energy sources (AmLi) and in other environments. Thus the need for the second solution noted above.

Since the general trend is for the allowable dose equivalent to be lowered, it is becoming increasingly important to have more accurate dose equivalent measurements.

Detailed Program Characteristics

An essential part of any solution to the dosimeter problem is the accurate characterization of dosimeter response as a function of neutron energy and/or a set of characterized environments in which the dosimeters can be calibrated. A facility for producing fast monoenergetic neutrons practically devoid of any gamma component exists at the Naval Surface Warfare Center (NSWC/CD) located 15 miles from NIST. The facility, a tandem accelerator, produces neutrons from 200 to 4000 keV and has been used by the Navy in the development of improved personnel dosimetric systems and research. Currently a standard on realistic neutron spectra is under development in the ISO which will give guidance on calibrating dosimeters in realistic spectra situations. Location of facilities suitable for realistic neutron spectro within the U.S. should be determined. Methods of using such facilities for standardized calibrations in cooperation with NIST should be determined or methods of establishing the basic capabilities at NIST should be sought. The NIST reactor might be available for some monoenergetic neutron calibrations or for generating some simulated spectra. Similarly a neutron generator (or accelerator) producing 14MeV neutrons could be used with appropriate moderators to generate realistic spectra.

An effort should be undertaken to review the realistic spectra standard under development and the NSWC/CD capabilities to evaluate approaches to providing standard calibration fields appropriate for accelerator-produced neutrons, low energy neutrons and various spectra existing at facilities. Capabilities should also be reviewed with respect to international guidance on reference fields. Based on this effort either existing facilities should be utilized or an effort undertaken to commission facilities at NIST.

U.S. Facilities, Staffing, and Funding

The proposed effort will take approximately 1 person year spread over 18 months to complete the study and evaluation. Following this it will take 2 person years for two years plus funding for hardware ($75k to $550k depending on approach).

Progress on MPD C.1 Since Publication of 1995 Needs Report

Neutron monitoring is a complex and continuing problem. Progress has been made in the development of recommendations for realistic calibration spectra and in general calibration standards. The MPD has been revised to reflect needs for neutron measurements around accelerators and for improved measurements for radiation fields around low energy isotopic sources.

MPD C.2: EXTREMITY RADIATION DOSIMETRY FOR PERSONNEL MONITORING

Program Summary

Radiation workers are sometimes required to manually manipulate or work in close proximity to radioactive materials (sources). This results in increased radiation exposure of the worker's extremities such as fingers, forearms, toes and lower legs. Present methods of monitoring such exposures are considered to be inadequate. Guidelines and regulations on the monitoring of radiation dose to extremities for occupational radiation personnel are felt to be incomplete. ANSI N13.32 has been developed by the Health Physics Society to address this problem and was recently approved. This standard parallels the existing ANSI N13.11 standard on whole body dosimetry. The National Voluntary Laboratory Accreditation Program (NVLAP) accredits dosimeter processors for whole body personnel dosimetry and has added extremity dosimetry to the existing program on a voluntary basis based on the ANSI N13.32 standard. Support of this standard was a major emphasis of the previous version of this MPD. Additional efforts are now underway to extend extremity monitoring to neutrons and to develop additional conversion coefficients for beta radiations using the extremity phantoms.

Detailed Program Characteristics

The current NVLAP personnel dosimetry program accredits approximately 80 dosimeter processors that supply personnel dosimeter badges (whole body dosimetry) to the 1.3 million occupational radiation workers in the U.S. The accreditation process is being extended to extremity monitors on a voluntary basis using the ANSI N13.32 standard. The program includes only photons and beta particles; neutrons have been excluded for the present. Several processors have met the accreditation criteria for extremity dosimeters.

N13.32 specifies a solid cylindrical rod phantom of PMMA, 19 mm in diameter by 300 mm length, to represent a finger. It specifies a solid cylindrical rod of aluminum, 60 mm in diameter by 300 mm length, nested inside a tube of PMMA with an inner diameter of 60 mm and outer diameter of 73 mm and 300 mm in length to represent bone and soft tissue of an arm or lower leg. In addition, the ISO recently proposed that the arm/leg phantom be represented by a water-filled pillar made up of a PMMA cylinder of 73 mm outer diameter, 2.5 mm wall thickness, 300 mm overall length, with 10 mm end walls. Conversion coefficients have been developed or are under development for the ISO phantoms under the auspices of the ISO; draft ISO 4703-3 for photons and draft ISO 6980-3 for beta particles. CIRMS members have been partial in development of some of these conversion coefficients. The conversion coefficients in the present ANSI N13.32 are derived from measurements. There is clearly a need to complete calculations of these factors in order to verify the validity of the experimental values.

Recently, a new work item proposal was approved by the ISO on the development of guidance for extremity dosimetry for neutrons. This is an area involving both basic questions (units of measurement) and a need for proper conversion coefficients.

CIRMS should support the ISO effort on neutrons, continue the development of conversion coefficients in support of the standards and determine how extremity monitoring for neutrons might mesh with current US interests. Experimental evaluation of neutron extremity monitoring using early drafts of the ISO standard should be undertaken. CIRMS should also continue to support the accreditation process using the N13.32 standard and assist in identifying and implementing changes as needed.

Progress on MPD C.2 Since Publication of 1995 Needs Report

A considerable amount of progress has been made in the area of extremity dosimetry. A testing standard (ANSI N13.32) has been completed and is the basis for a prototype accreditation program operated by NVLAP. A meeting was held at NIST (3/95) to discuss this program and other accreditation program changes. Progress has also been made in the computation of conversion coefficients for the rod and pillar extremity phantoms. The MPD has been modified to emphasize these changes along with a current effort to consider neutron extremity doses.

MPD C.3: INTERCOMPARISON TRANSFER STANDARDS FOR NEUTRON SOURCE CALIBRATIONS

Program Summary

The calibration of personnel dosimeters and area survey meters used for radiation protection purposes in neutron fields is difficult, for a number of reasons. The devices used for measurements in neutron fields have dose equivalent responses that are dependent on the neutron energy spectrum and on the scattering environment at the point of measurement. In addition, the reference calibration neutron sources maintained by NIST are not available for routine calibration or intercomparison measurements. These measurement services are supplied by secondary calibration laboratories.

In order to ensure the consistency of calibrations performed by secondary calibration laboratories with NIST standards, measurement quality assurance (MQA) interactions between the laboratories and NIST must take place. When consistency is established at a level that is mutually agreed upon, the secondary laboratory maintains the calibration unless or until a discrepancy is detected by the periodic MQA interactions. This system has worked well in maintaining the consistency of secondary laboratories with NIST for some, but not all, radiation types.

The MQA program for photon (x-ray and gamma-ray) radiations has been in place for many years, and the consistency between NIST and the secondary laboratories is quite good. The situation for neutrons, however, is more complex. The neutron reference radiations maintained at NIST are those recommended by ISO 8529-1. Most of the physical characteristics of these sources have been documented and are available. However, because of the complex interactions that take place as a result of neutron irradiations, additional information about the irradiation conditions must be determined. The critical elements of a neutron calibration include more than the radiation source spectrum and intensity. The calibration is dependent upon having knowledge of the interaction of the neutron source with its surrounding material, the irradiation room, the phantom (for dosimeters), and the detector itself. The methods required for neutron calibrations are discussed in ISO standards 8529-1, 2 and 3.

An MQA program for neutron dosimetry needs to incorporate methods that will either incorporate or evaluate the effects of all of the items mentioned previously. Each neutron calibration facility is virtually unique, and each of the items mentioned as having an effect on the calibration needs to be considered in the design of a method for MQA measurements. If a technique is used to measure the neutron fluence free-in-air with a device (such as a precision long counter) that has a relatively flat response as a function of neutron energy, then the variable effects of absorption, scattering, secondary radiation production and other effects, will not be determined by the measurement. If devices are calibrated that have a substantially different energy response, then corrections may need

to be applied. Therefore, a method needs to be developed that will permit evaluation of all of the variables or that has a response to the variables that is close to that of the devices calibrated.

Detailed Program Characteristics

Several efforts have been made to establish MQA methods for neutron dosimetry. Previously, a phantom with TLD elements embedded at various depths was evaluated under the auspices of this MPD. Unfortunately, this method proved to be difficult to interpret and the response of the device was complex. Currently a direct method is under study. Typical personnel dosimeters have been irradiated under nearly identical conditions at NIST and PNNL. The results of this study are presently being evaluated. It is necessary to continue these studies and to extend them to area survey meters.

Follow-on experiments will determine optimal reader parameters and appropriate irradiation and readout protocols for use of the TLD system as transfer standards in intercomparison measurements and for proficiency testing of calibration laboratories seeking accreditation by NVLAP for dosimetry.

Additional efforts will be undertaken to evaluate the use of a survey meter as a transfer standard for general calibrations of neutron survey meters. Another approach that will be further evaluated is the use of the tissue equivalent ion chamber. Current research efforts on electronic dosimeters will result in detector based methods of neutron dosimetry. The devices under consideration (combinations of diodes, ion chambers, and multi-cell tissue equivalent proportional counters) will have energy responses that are different from conventional dosimeters and different from instruments. Ensuring that the transfer standards are suitable for these devices will require additional investigations in the next 1-3 year time period.

U.S. Facilities, Staffing, and Funding

NIST and PNNL will be primary participants in these efforts. Other laboratories and vendors will be involved as the electronic dosimeter evolves. The laboratories will need to perform experimental irradiations, establish a pool of transfer dosimeters/instruments and develop capability to analyze and tabulate the results. The program will require one person-year per year ($200k/y) and appropriate funds for equipment and supplies ($150k).

Goals: The goals will be to develop techniques that will permit transfer of neutron calibrations between NIST and secondary laboratories while maintaining accuracy that is appropriate to the measurements.

Progress on MPD C.3 Since Publication of 1995 Needs Report

The original effort on transfer standards was completed and was not successful. The MPD has been revised to include intercomparisons with both instruments and passive dosimeters. Currently efforts are underway with a direct method of intercomparisons using personnel dosimeters.

MPD C.4: IMPROVEMENTS IN IN-VIVO RADIONUCLIDE METROLOGY

Program Summary

Non-invasive *in-vivo* radiobioassay (whole-body counting) of personnel working with radionuclides or materials with potential radioactive contamination is a primary method dosimetrists employ for routine occupational monitoring and crisis assessment. The variability among "homemade" and *de facto* reference phantoms can account for up to 200 percent differences among measurement laboratory results. Measurement comparability and consistency can be ensured through calibrations based on national standard realistic human-surrogates (phantoms). In addition, site-specific (organ-specific) quantitative assessment requires new measurement technology and 3-D tomography. The solution to these problems is the development of the technological and measurement quality assurance bases for quantitative site-specific *in-vivo* radiobioassay. This is a recommendation of the International Workshop on Standard Phantoms for *In-Vivo* Radioactivity Measurements [Health Physics, **61**, 893 (1991)].

The benefits of this initiative to personnel safety include: comparable quality of dosimetry assessments; assessment of dose to individual critical organs; transferable dosimetry histories for employees; refinement and verification of biokinetic models. Technologies developed for methods, software, and hardware will be directly transferable to the national radioactivity waste management initiative and the medical diagnostics community.

Substantial progress has been made on this measurement program over the past few years. Standards working groups have been established through the HPSSC (HPS standards committee), work has been performed on materials development, modeling studies have been completed and work has been performed on standardization measurements. Several of these efforts are in progress and work must continue toward completion of these efforts and implementation of guidance in the field.

Detailed Program Characteristics

Research and development challenges include innovations in radionuclide labelled polymer manufacturing and quality control technology; new high-resolution detector technology; flexible computer based (Monte Carlo) calibration of detection systems; and 3-D topography technology for irregular / heterogeneous subjects. The results of materials and computational research and instrument development will yield rewards in many related fields. Polymer science and industry will be challenged to develop advanced formulation and quality assurance technologies because: (i) techniques are needed to manufacture polymer-based phantoms that accurately simulate the density, radiation scatter (effective Z) and attenuation of human tissues; and (ii) manufacturing techniques must be developed to ensure consistency and reproducibility. Radiation detection

scientists must develop detectors that produce high resolution x-/gamma-ray spectra without having to be refrigerated at liquid nitrogen temperatures. Measurement quality assurance and accreditation programs for *in-vivo* radionuclide metrology will depend on standard phantoms and computational modeling techniques to ensure measurement consistency. Coupled with this is the need for uniformly labeling the phantom materials with known and traceable quantities of radionuclides.

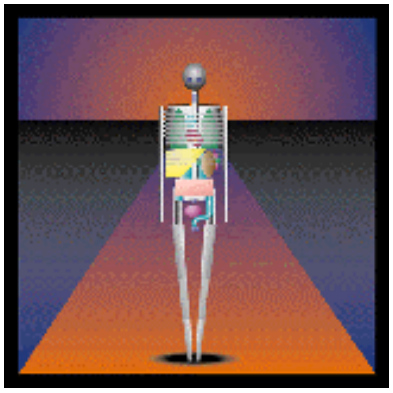
In-vivo radionuclide measurement depends on direct measurement of radiation emitted from internal depositions. This initiative will be directed at these measurements and will be the summation of several separate but coordinated efforts. Preparation of the American National Standard on manufacturing criteria for BOMAB and Realistic Human Torso Phantoms; these efforts are presently underway. Progress has also been made on the development of methods to label phantom inserts homogeneously, and on methods to assess homogeneity of phantom inserts.

Development of internal detection probes for lung counting has progressed slowly. Although the computational techniques are developed, development of a standard phantom family and comparative measurements with Monte Carlo calculations plus interlaboratory comparisons and calibrations will require 5 years. Comparison of calibrations of standard phantoms to surrogates in the phantom library and to real animal/human exposures, and development of quantitative 3-D topography technology is underway, but will not be completed for 5-10 years.

This program will facilitate and coordinate the efforts that are being implemented in a variety of laboratories among different agencies. While NIST is developing standard reference materials, the BRMD is working on the development of a family of BOMAB phantoms, DOE and RESL are piloting a radiobioassay laboratory accreditation program based on the ANSI N13.30 standard that has been approved since this effort was initiated; LLNL has completed computational expressions of calibrations of individual subjects, and PNL has established a national phantom library. These latter efforts must continue to practical applications while maintaining a connection with national standards to ensure traceability of measurements.

U.S. Facilities, Staffing, and Funding

Currently, work is ongoing on new phantom materials, American National Standards, techniques for assessing homogeneity and content of phantom inserts, and Monte Carlo calculations. These efforts need continuing coordination and communication to ensure that measurement quality assurance aspects are properly coordinated and that measurement methods are addressed. Coordination and detector development will require an estimated 1 to 2 person years per year for



C.4¾ Computer phantom used for modeling personnel radiation exposures.

approximately 10 years. This is in addition to ongoing efforts. Equipment, Standard BOMAB and Realistic Human Torso Phantom; micro-high resolution high temperature semi-conductor / diode gamma-ray detection probes; high resolution gamma-camera and software, advanced Monte Carlo software ($3M). Laboratories: NIST, LLNL, BRMD, RESL, PNNL.

Progress on MPD C.4 Since Publication of 1995 Needs Report

Considerable progress has been made in the area of in vivo metrology. Three ANSI standards on phantoms are nearing completion, a computational method for counter calibration was completed and progress has been made on the formulation of improved phantom materials and methods of phantom comparisons. The ANSI N13.30 standard on testing of bioassay labs was approved and DOE is undertaking a pilot program using this standard. Future progress is expected on the completion of the standards and the initiation of accreditation programs.

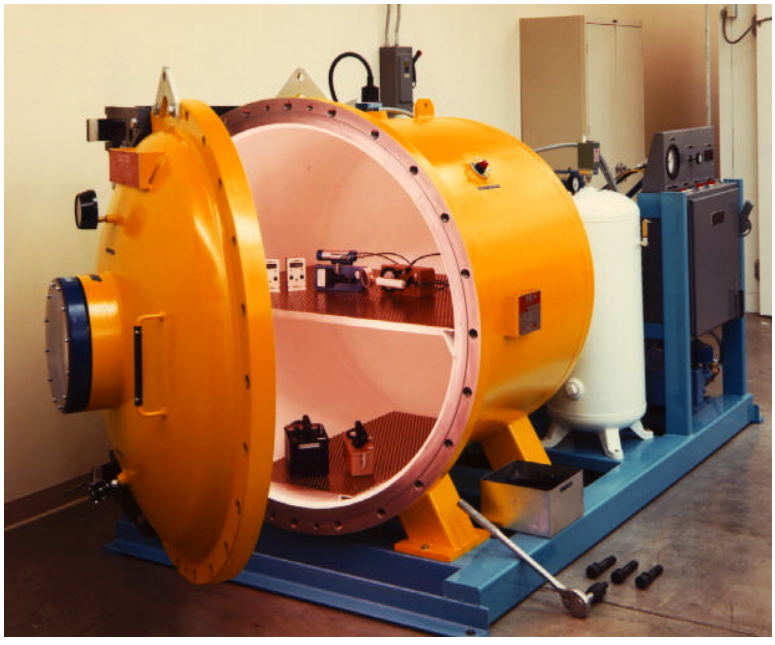
MPD C9: TYPE TESTING PROGRAM FOR INSTRUMENTS

Program Summary

It has been shown that the performance of instruments is not well characterized and that performance is more variable from instrument to instrument of the same model than one would expect. Although most users agree that defining the performance of instruments (type testing) would be of value, the regulators and user community have not established a national program. By establishing a working group, it will be possible to define an approach that will improve the performance of radiation measuring instruments in terms of data quality and reliability. The need for this effort has become more acute with the advent of the electronic dosimeter, ED. The ED is basically an instrument, and it is now under consideration for primary dosimetry.

Detailed Program Characteristics

Past studies have shown that the performance of instruments is not well characterized and that it is more variable from instrument to instrument of the same model than one would expect. Type testing of the instrument can provide quality data that will delineate the performance envelope of the tested device over a selected range of influencing variables. Performance standards (ANSI N42.17, ANSI N13.27, ANSI N42.20, etc.) have been written that can serve as a basis for type testing of instruments. Although most users agree that type testing would be of value, the regulators and user community have not established a national program. DOE facilities have established an informal effort that is intended to standardize the instruments in use at participating facilities. This program uses the type-testing concept, but is limited in scope in terms of the user community. Consideration of the electronic dosimeter for primary dosimetry increases the importance of type testing since this is critical in establishing the performance of the dosimeter. Knowing the performance of the instru-



C.9¾ Type testing of radiation detection instruments at the Battelle Pacific Northwest National Laboratory.

ment or dosimeter and the expected conditions of use permit the user to select an instrument or electronic dosimeter that will meet his needs. This is important since changes in influencing variables during use will affect the accuracy or even the validity of the readings.

Presently Oak Ridge National Laboratory and Pacific Northwest National Laboratory have capability to perform comprehensive type testing and do perform such testing on a limited basis. Many facilities have capabilities for a limited scope of testing. The testing is generally performed to address specific customer needs and is not aimed at disclosure of the full set of instrument operational characteristics to the general community. Recently, DOE has established an effort to provide type test data on the Internet. This will provide data to a larger segment of the community.

In order to have type testing meet the expectations and needs of the user community several steps should be taken:

- Define the broad scope of user needs for such testing.
- Define need for tests based on actual facility conditions as opposed to testing against criteria in a published standard.
- Establish quality control expectations and methods for testing laboratories (NIST traceability).
- Determine conditions under which third party testing should be required.
- Recommend methods for the dissemination of testing data (certified data through vendors, independent publication, publication on Internet, etc.)
- Determine feasibility of multiple test sites and number of instruments for a valid test.
- Determine need for and a rational basis for periodic retesting of devices.
- Determine how to appropriately connect routine tests with the type test results.
- Determine if regulatory action is justified and work with regulators as required.
- Determine how type testing should be applied to the ED.
- Evaluate the use of total uncertainty for instrument evaluation

Establishing a working group representing users, NIST, manufacturers and regulators to resolve the above issues. This will aid in defining and developing a usable program and in identifying NIST needs in providing standards for measurement quality assurance. It is anticipated that accreditation of the testing laboratory(s) can be handled through NVLAP or one of the professional societies.

U.S. Facilities, Staffing and Funding

The Council of Ionizing Radiation Measurements and Standards can assume a leadership role in this challenge by facilitating the resolution of the identified issues and by recommending program-operating characteristics for a national program. A committee with broad representation (NIST, ORNL, PNNL, etc.) should be assembled to address the various issues and develop specific recommendations including maintenance of "traceability." The committee could perform most of its activities by correspondence (Internet) with only two or three meetings. Funding of approximately $30K would be needed to pay for organization and holding of the meetings.

Goal: Implementation of a type testing program would put the U.S. in a position comparable to other nations and would improve the status of U.S. manufactured instruments.

Progress on MPD C.9 Since Publication of 1995 Needs Report

The type testing of instruments is a new MPD and reflects the growing concern over type testing as users attempt to standardize their measurement programs. The increasing interest in the electronic dosimeter has also emphasized the need for the type testing of instruments. A meeting cosponsored by CIRMS was held in October of 1997 to discuss issues related to the electronic dosimeter including type testing. There is a general need for resolving the type testing issues and developing a consensus policy. The exact role of measurement quality assurance in the overall test program must also be resolved.

MPD C.17: IMPROVE RADIATION MEASUREMENT INFRASTRUCTURE FOR OCCUPATIONAL RADIATION PROTECTION

Program Summary

The infrastructure that supports radiation measurements for purposes of occupational radiation protection has two major components: standards and accreditation programs. These elements are needed to ensure a consistent measurement system that meets defined needs for radiation environments in terms of measurement uncertainty. Although many of the technical details are included in individual measurement programs and described in the relevant MPDs, there are overall elements requiring individual attention.

Standards

Radiation calibration standards are required to ensure that calibrations (and interpretation of occupational risk) are consistent on both a national and an international basis. The standards must describe the generation and calibration of radiation fields in terms of standardized quantities and the use of a consistent set of conversion coefficients to interpret the fields in terms of worker risk. The ISO is actively developing such standards and several CIRMS members are active on the committees. The work of the ISO must be encouraged and expanded to meet ongoing needs in the standardization of measurement and calibration methods. This work must be monitored to ensure proper representation of U.S. interests.

Accreditation

Accreditation provides a method of ensuring that calibrations, dosimeter processing or test measurements are performed in a quality manner consistent with established standards or criteria thus providing assurance that the results are consistent with national needs. In addition it is necessary to ensure that the accreditation programs are consistent, cost effective, and appropriate in terms of national and international needs. There are presently four national programs that accredit secondary calibration laboratories in the area of ionizing radiation dosimetry in the protection range. Although the critical elements of a complete measurement quality assurance (MQA) program are required for accreditation under each of these programs, they do not use the same general or specific criteria to evaluate candidate laboratories. The criteria are similar, but not identical. Questions have been raised about the comparability (equivalence) of accreditation granted by the various programs. An obvious major improvement would be the adoption, by all the programs, of ISO/IEC Guide 25, which establishes general criteria for laboratory performance. Through meetings and information exchange CIRMS has made progress in this area; with all of the programs in some stage of incorporation of ISO/IEC Guide 25. Other related questions are not as easily resolved, and need further study.

A recent innovation is the consideration of total measurement uncertainty as a basis for dosimetry system approval. Germany has developed pattern tests based on total system uncertainty that will be used for approval of dosimetry systems in the future. The HPS is developing a standard for evaluating dosimeter uncertainty and the IEC is working on a standard for evaluating the uncertainty of measurements made with instruments. These standards consider a greater range of influence quantities than the NVLAP and DOELAP standards and provide a rational basis for evaluating dosimetry against guidance by the ICRP.

Detailed Program Characteristics

CIRMS can ensure the development of needed standards appropriate to national interests by participating in the standards development process including:

- Identification of needed standards that support the radiation measurement infrastructure needed for the protection of occupational workers.
- Active participation in the development of standards including the development of supporting data needed in the standards such as conversion coefficients.
- Participate in the technical review of standards to ensure that they capture the latest technology and specific needs of the users. Review of international standards is particularly important to preserve the interests of the U.S. radiation protection community.

In terms of accreditation, the four national programs (in chronological order) developed to accredit secondary calibration laboratories are administered by the American Association of Physicists in Medicine (AAPM), the Conference of Radiation Control Program Directors (CRCPD), the Health Physics Society (HPS), and the National Voluntary Laboratory Accreditation Program (NVLAP). Respectively, the criteria used to evaluate laboratory performance for each program were developed by an AAPM committee, a CRCPD committee, an HPS committee, and a national consensus group. The fact that NIST was closely involved in the development of each set of criteria provided a degree of uniformity, and guaranteed that each program required inclusion of the critical elements of a complete MQA program. Thus, the four sets of criteria are similar, but not identical. This gives rise to questions about the comparability (equivalence) of accreditation granted by the four programs. However, it is not clear whether it is desirable that these different accreditation's be equivalent. In a CIRMS special meeting it was noted that the technical expertise required of assessors is unique to most of the programs. This topic needs further consideration. In addition to the question of comparability other important factors affecting the programs are:

- Need for the accreditation of the accrediting programs. Currently a national effort is underway to accredited accrediting organizations using ISO Guide 58.

This effort needs to be reviewed by the affected programs to determine the value to our efforts.

- Improving the cost effectiveness of the accreditation programs is always a concern. The AAPM has developed a model using round robin intercomparisons (see Addendum) and other programs should be assisted in reviewing this process as appropriate.
- Acceptance of the programs by the regulators and the customers. An accreditation certificate is not universally recognized as an indicator of program quality.
- The need for and value of international acceptance of the accreditation programs.
- Consideration of total uncertainty as an evaluation parameter for dosimetry and other measurement systems.
- Consideration of new technologies such as the electronic dosimeter and how / or if they should be integrated into existing accreditation programs.

At the time the four programs were developed, there was no national or international recommendation or guidance regarding criteria for calibration laboratories. Subsequently, ISO / IEC Guide 25 was issued, entitled "General Requirements for the Competence of Calibration and Testing Laboratories." Laboratories meeting the requirements of that Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards. Those *general* criteria are of considerable value, but additional criteria that are *specific* to ionizing radiation calibrations are also needed to assure meaningful, consistent evaluations of laboratories that perform such calibrations.

Additional ISO / IEC Guides including: 58, "Calibration and Testing Laboratory Accreditation Systems-General Requirements for Operation and Recognition (Revision of ISO / IEC Guides 38, 54, and 55)" and 43, guide on proficiency testing, will affect the operation and performance of the accreditation programs and must be considered to properly evaluate their impact on all four programs.

The HPS was the first program to adopt ISO / IEC Guide 25 as its general criteria, and has developed pertinent specific criteria. The other four programs are in various stages of adopting ISO / IEC Guide 25 as their general criteria. Studies should be initiated that will address the factors identified in the bulleted list.

The use of total uncertainty as the basis for measurement technique evaluation and approval needs to be fully evaluated. The effort will require a review of existing standards, draft standards and guidance from ICRP and NCRP. It will also be necessary to review existing testing data and test capabilities within the community to determine if it is practical to implement a type testing regime. This would be Phase I. Phase II would be to develop the requirements (standards) to implement such a program

and perform some prototype tests. Phase III would be to implement a program based on the type testing—quality control test philosophy if results of the other studies are favorable.

U.S. Facilities, Staffing, and Funding

CIRMS members need to meet with international standards developers to make sure needed standards are identified and approved for development. CIRMS members have been active in the development and review of conversion coefficients used in ISO standards. This activity needs to continue. Members have also been active in the development of international standards for beta, photon and neutron reference radiations. Review of standards has resulted in changes that ensure compatibility with U.S. practice and U.S. regulations. In general this is a continuing effort involving a moderate amount of time from a large number of individuals. In terms of identifying new standards a meeting should be held that will provide time to discuss and evaluate proposals to ensure that efforts meet the needs of CIRMS.

Adoption of ISO/IEC Guide 25 by the four programs has been coordinated by the CIRMS Occupational Radiation Protection Subcommittee. This coordination, identification and resolution of events affecting the accreditation programs should continue. The study group should consist of persons who are actively involved in laboratory accreditation programs and have a working knowledge of performance criteria. Representatives of each of the four programs should serve in the study group. The estimated cost for the necessary meetings and coordination is $12,000 per year for the next few years. Addressing these issues at an annual meeting as the major topic will assist deliberations.

An *ad hoc* working group should be formed through CIRMS to study the pattern testing/type testing philosophy and make recommendations. The group could meet 2-3 times over the course of a year to develop a study paper at a cost of $90k for staff time and $35k for travel.

Goal: The goal of the MPD will be to improve the usefulness of standards to the measurement and calibration process and improve the compatibility and recognition of the accreditation programs.

Progress on MPD C.17 Since Publication of 1995 Needs Report

The specific issues related to accreditation of calibration or testing laboratories have been combined into one MPD to represent the broader picture and the general impact such activities have on the general radiation measurement infrastructure. Progress has been made on opening discussion of the programs in a broader context including a special meeting at the HPS meeting in 1995 and a topical meeting on secondary calibration laboratories in November of 1997. The new MPD will also include standards; a topical meeting was held on this subject in November of 1996. A special meeting was also held in November of 1997 to discuss needs in international standards in the context of occupational radiation protection. Future efforts will continue to look at means of improving the comparability, recognition, cost effectiveness, etc. of programs. Efforts will also include a look at evaluating total uncertainty as a basis for evaluation of measurements in radiation protection.

MPD C.18: IMPLEMENTATION OF ELECTRONIC DOSIMETRY FOR PRIMARY DOSIMETRY

Program Summary

The electronic dosimeter (ED) has become a leading choice for secondary dosimetry and is under active consideration for primary dosimetry at many locations. Recent advances in electronics have greatly enhanced the capabilities of the ED and made them an important tool in dose control in the workplace. Continuing improvements in capabilities and reliability coupled with the lower detection levels compared to passive dosimeters, make them an important consideration for primary dosimetry. However, they still have important limitations in terms of environmental (primary concern is radio-frequency susceptibility), low-energy photon response, beta response and neutron response. The newer technologies promise to eliminate these limitations and administrative controls would permit the use of existing EDs in many workplaces today. It is important that an orderly transition into use of the ED be accomplished to maintain public and worker confidence and to maximize cost effectiveness for the users.

The electronic dosimeter does not fit well with the current standards and accreditation schemes as formulated. The ED and other new dosimeters may require changes in the present accreditation schemes and may require formal type testing. Tracking of the limitations in the ED and reviewing the requirements for the support infrastructure (beyond the formal performance testing issues) are also needed.

Detailed Program Characteristics

There are several actions or activities that are needed in order to facilitate the orderly transition into primary dosimetry using the electronic dosimeter. Several of these needs are highlighted below:

1. Identification of needed standards that support the radiation measurement infrastructure needed for the protection of occupational workers using the ED.

2. Consideration of how the electronic dosimeter can be optimally integrated or if they should be integrated into existing accreditation programs.

3. Mechanisms to identify limitations and progress made in eliminating the limitations (deficiency reports, technical reports, vendor performance, product improvements, etc.).

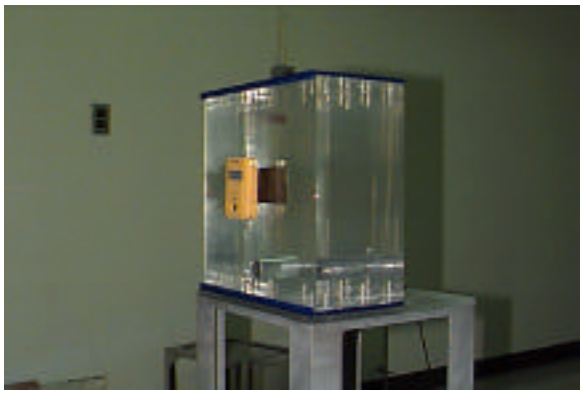
4. Mechanisms to ensure that the ED is producing data that are as good as and reliable as that obtained from existing dosimetry systems.

5. Identification of operational elements that are needed to ensure that the ED is used appropriately and to ensure the continuing reliability of the ED.

6. Identification of interfaces with international dosimetry database groups and establishment of the appropriate interfaces.

7. Assistance for users in the integration of the ED into their active programs meeting both dosimetry and legal requirements.

In order to address items 3, 4 and 5 above, a mechanism must be established to track and analyze field performance data for the ED. CIRMS should review approaches and help establish an appropriate mechanism. Approaches could include formal reporting through a regulatory agency or industry group, establishing a website or mail mechanism for collection of data, etc. Beyond the reporting of data an entity must be established to collate the information and make it available to all stakeholders. CIRMS can help with item 1 by identifying the scope of needed standards, recommending their development to writing groups and participating in the development and review of the standards. Similarly, CIRMS can review accreditation needs (item 2) and recommend changes to enhance existing programs and ensure that they meet ED needs. Communication of the issues can also be facilitated by the periodic sponsorship of workshops that review the status of the ED and address issues related to their deployment and use within the nuclear industry. A workshop sponsored by CIRMS, NRC and NIST was held in October of 1997 to begin the process of addressing issues related to the use of the ED for primary dosimetry.

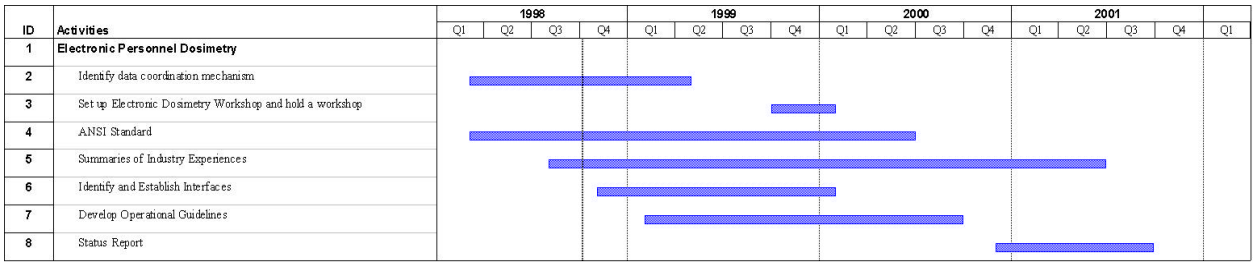


C.18.1¾ Electronic personnel dosimeter on a lucite slab for calibration in a beam at Battelle Pacific Northwest National Laboratory.

U.S. Facilities, Staffing, and Funding

Successful accomplishment of this MPD will require the participation of user and manufacturer representatives along with participation by regulatory groups. It will take voluntary participation by several individuals plus funded participation to collect user data, analyze the data and hold periodic workshops. Establishing a data collection mechanism (website) would best be handled through a regulatory or industry group. It is estimated that this activity would cost about $25k on an annual basis with start up costs of $40k. Workshops should be held about every 18 months at a cost of $10-20 K depending on the scope and location of the workshop.

Goal: The goal of the MPD will be to accomplish the orderly integration of the ED into use for primary dosimetry applications.



C.18.2 – Roadmap for electronic personnel dosimetry.

D. INDUSTRIAL APPLICATIONS AND MATERIALS EFFECTS MPDS

INTRODUCTION TO INDUSTRIAL APPLICATIONS AND MATERIALS EFFECTS MPDS

The Council on Ionizing Radiation Measurements and Standards (CIRMS) considers all aspects of ionizing radiation which involve radiation effects, including uses in the medical community for diagnostic, therapeutic or palliative purposes, and the monitoring of exposure of persons working with ionizing radiation or the general public from naturally occurring radiation sources. To distinguish its mission from that of the other sub-committees of the CIRMS Committee on Science and Technology, the "Radiation Effects" sub-committee renamed itself as the "Industrial Applications and Materials Effects" (IAME) sub-committee. As such, this sub-committee deals primarily with the use of radiation in industrial processes, in contrast to applications related to effects on humans. Three forms of radiation encountered within the industrial community are taken into account:

Accelerated Electron Beams
Gamma Rays from Radioactive Isotopes
Neutron and Mixed Field Effects

Accelerated Electron Beams

Many industrial applications rely upon high current electron beam accelerators which provide ionizing radiation to enhance the performance and / or market value of materials or processes. These applications mainly involve the use of either high current electron beam accelerators or gamma irradiation, most typically generated from ^{60}Co radioactive sources. At an IAME sub-committee workshop held in October 1997, estimates of the high current industrial usage of electron beam accelerators indicated that on a worldwide basis there were:

High Current Electron Beam Accelerator Installations

Voltage Range	Number of Units	Average Beam Power
0.1 to 0.3 MeV	300	100 kW
0.4 to 5.0 MeV	700	40 kW
5.0 to 15 MeV	35	15 kW

These are supported by a multitude of low current accelerators used primarily for research purposes, such as the Van de Graaff generators.

Electron beam accelerators in the 0.1 to 0.3 MeV range are sufficiently low in voltage such that they can be housed in lead shielding to provide the needed safety for operators from the resultant x-rays generated when electrons impinge upon target materials. These accelerators utilize elongated filaments and have been made at up to three meters in width. The limited penetration of 0.3 MeV electrons (approximately 430 microns or 17 mils) constrains these devices to applications involving thin films, such as the surface curing or crosslinking of coatings, inks and adhesives or the crosslinking of polymeric films used in some shrink film applications. However, beam currents as high as 1.3 amperes have been achieved. Since product through-put is proportional to beam current, production rates in excess of 700 meters per minute have been noted, depending upon the response of the processed material to ionizing radiation and appropriate under beam handling process equipment.

Mid-voltage, high current accelerators have been produced with total beam power (voltage times current) of 200 kW. The predominant use of such high current, mid-voltage accelerators has been to crosslink the jacketing on wire and cable in order to render such insulation resistant to heat distortion and melting, should a short or unusually high current be encountered which would heat the conductor. The most common accelerator for these wire and cable applications is a 1.5 MeV device. While lead shielding has been used for accelerators up to 0.8 MeV, shielding for these and the higher voltage accelerators is thick walled concrete. The thickness of the concrete or shielding is proportional to the accelerator voltage as prescribed in the National Council for Radiation Protection and Measurements, Report No. 51, Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities (NCRP Publications, Bethesda, MD). The maximum voltage attained at these high beam currents (up to 100 milliamperes) is 5.0 MeV (but at reduced amperage), which implies beam penetration of 1.7 centimeters (0.7 inches) for unit density materials.

A diversity of other significant industrial operations employ mid-range, high current accelerators as part of manufacturing processes. For example, tire companies (Bridgestone, Goodyear, Michelin) use such electron beam processing to partially cure tire components in extruded form before they are plied into tires, then molded and finally cured. Shrink film used in food packaging applications (the Cryovac Division of the Sealed Air Corporation) and heat recoverable tubing (the Raychem Corporation) used to insulate electrical connectors also rely on such high current accelerators to crosslink materials, notably polyethylenes and compositions thereof. There are numerous other industrial applications for these high current, mid-voltage accelerators, including use in the sterilization of medical devices.

For the most part, the higher voltage, high current accelerators are being considered for developing markets wherein their higher beam penetration is of consequence (10 MeV giving 3.5 centimeters electron penetration in unit density material). These markets

include medical device sterilization, food irradiation (where experimental work is being conducted on food irradiation with 10 MeV electron beams at Iowa State University), and curing of fiber reinforced composite plastics. Several companies have demonstrated the capability of producing modest current, higher voltage, electron beam accelerators. At the electron beam workshop, it was noted that there were indeed numerous existing and potential accelerator suppliers, but there was a lack of coherent market development.

Thus, no specific needs pertaining to accelerator design nor development will be addressed in this report. Relative to market demand, there is perhaps an excess diversity of high-current industrial electron accelerator supply and capability for envisioned and existing end-uses.

It was also observed that for a majority of low and mid voltage electron beam industrial applications, product properties and performance are the requirements and not dosimetric parameters. For example, industry accepted use of solvent rubs is a criterion for indicating the complete cure of a low voltage electron beam cured coating. The modulus of elasticity, which for thermoplastics such as polyethylene is determined above the melt transition of the thermoplastic, is used to indicate the crosslinked state of films, shrink tubing and wire and cable insulation. Only in those areas which must comply with some regulatory requirements, such as in the sterilization of medical devices and in the elimination of potentially hazardous bioburdens from foodstuffs, are dosimetric requirements essential.

Gamma Irradiation

For the most part, the industrial use of gamma irradiation relies on well-established irradiator designs in which products are exposed to gamma rays generated from the decay of ^{60}Co radiation sources. There had been a modicum of interest in the use of ^{137}Cs. The use of ^{137}Cs in industrial environments has been limited because of concerns regarding the solubility of cesium chloride in the event of capsule failure.

In contrast to accelerated electron beams, gamma irradiation has:

- Significantly greater depth of penetration (product stacks up to approximately one meter are common even at relatively high product densities).
- Dose distribution uniformity in these thick cross-sections.
- Ability to be scaled down for research purposes with a readily available installed base of research scale systems.
- Lower dose rates of approximately 10 kGy per hour (in contrast to EB dose rates of 10 kGy per second).

According to the preeminent supplier of ^{60}Co and designer of multi-purpose gamma irradiation facilities, MDS Nordion (Kanata, Ontario, Canada), there are over 180 large-

scale gamma processing facilities in over 47 countries throughout the world. These facilities are used mainly for the sterilization of medical devices, including syringes, surgical gloves, IV sets, surgical kits and trays. Approximately 45% of the sterile disposable medical devices manufactured in North America are sterilized with gamma irradiation. A number of major suppliers of medical devices own and maintain their own ^{60}Co gamma irradiation facilities.

Within North America, many ^{60}Co irradiation facilities also perform some food irradiation. One such ^{60}Co irradiation processing facility dedicated primarily to food irradiation is Food Technology Services, Incorporated (Mulberry, FL). Other facilities deal with food items such as spices. The use of ^{60}Co for food irradiation is being extended to Mexico. Research and development is being conducted on food irradiation involving ^{60}Co irradiation systems at the Canadian Irradiation Centre (Ville de Laval, Quebec, Canada) and at the Canadian Department of Agriculture's Food Research Centre (St. Hyacinthe, Quebec).

Most of the industrial applications relying upon gamma irradiation involve uses for which there are regulatory controls, such as the sterilization of medical devices and food irradiation. Thus, dosimetric release parameters are essential. In addition to the commercial and pilot-scale gamma irradiation facilities, there are many smaller self-contained or panoramic gamma facilities used for a variety of other applications including the radiation hardness testing of semi-conductors, materials testing, and dosimetry development studies.

Neutron and Mixed Field Effects

Neutron Effects on Steel: There are currently 109 operating nuclear power reactors in the United States that are being used for electric power generation. A principal concern regarding the continued, safe operations of these reactors is the impact of neutron irradiation on the structural integrity of the reactor's pressure vessel. The study of neutron-irradiation effects on pressure vessel steel can only be adequately addressed through a national commitment to a long-term measurement and monitoring program conducted over an extended period of time. Unlike other industrial applications, short-term programs of limited scope, while useful for providing certain engineering data, cannot fully address the strategic and social needs for ensuring nuclear reactor operational safety.

Mixed Field Effects: Of increasing industrial concern and of national security and military importance are the effects of irradiation on components used in the space and commercial environment, in particular sensitive electronic devices. These exposures often involve mixed fields of irradiation, gamma, neutrons and, in space, also high-energy protons. Here unique measurement and radiation effects problems confront the irradiation community.

MEASUREMENT PROGRAM DESCRIPTIONS (MPDS)

In the Council on Ionizing Radiation Measurement and Standards January 1995, "Report on National Needs in Ionizing Radiation Measurements and Standards," four measurement project descriptions were outlined in the "Radiation Effects" section:

D.1 High-Dose Calibrations for Electron Beam Processing.
D.2 Radiation Measurements for Gamma Radiation Processing.
D.3 Gamma-Ray Dosimetry in Mixed Fields for Radiation Hardness Testing.
D.4 Neutron Dosimetry for Reactor Pressure Vessel Surveillance.

Because of progress made in these four areas and the emergence of some other areas of industrial interest, the Industrial Applications and Materials Effects (IAME) subcommittee reviewed a variety of use and effects areas:

Areas Considered

EB Cured Polymeric Materials
Medical Device Sterilization
Hardness Testing
Steel Embrittlement
Waste Treatment
Food Irradiation
Chip Doping

Within the context of this review, a variety of methods being used to determine the dose or relative exposure of materials to radiation were taken into consideration:

Dosimetry Methods

Radiochromic films
Polymethylmethacrylate
Alanine pellets and films
Diamond
Real-Time-Monitoring
Chemical dosimeters
Optically Stimulated Luminescence
Calorimetry
Track etching
Radioactivity measurements

As a result, the Industrial Applications and Materials Effects sub-committee determined:

1. To become more focused on program needs by combining parts of MPDs D.1 and D.2 to create a new MPD D.5 which is targeted specifically at the measurement and quality needs of the medical device sterilization community.

2. To revise MPD D.3 to expand its coverage to radiation effects in the space environments.

3. To revise MPD D.4 to be current with requirements published by the U.S. Nuclear Regulatory Commission.

4. To create a new MPD D.6 to deal with the measurement issues resulting from the increased use of ionizing radiation for a wide variety of uses involving pollution prevention (P2).

5. To create a new MPD D.7 on food irradiation.

The details of these two revised MPDs, D.3.1 and D.4.1, and of the three new MPDs, D.5, D.6 and D.7 are discussed below.

MPD D.3: RADIATION HARDNESS TESTING AND MIXED-FIELD RADIATION EFFECTS

Radiation Hardness Testing for Space Environments

Program Summary

The overall success of future space missions, including spacecraft designed for deep space exploration as well as for extended, near-earth orbits, is strongly predicated on the ability of advanced electronic components utilized in the fabrication of spacecraft and payload instrumentation and control systems to be able to operate at full capacity for extended periods of time within the unique and extremely harsh radiation environment of interplanetary space. The declining availability of radiation facilities, especially particle accelerators, is a cause of concern for space program managers attempting to qualify high performance technologies for use in future space-based electronic systems. With a declining industrial base of radiation-tolerant (radiation-hardened) electronic components, space systems engineers are forced to turn to commercially-available parts for the necessary electronics. As such, these commercially-available devices require careful radiation testing, especially since their reduced size and operating power increase their vulnerability to space-borne radiation.

This issue has recently been the subject of intense discussion within DoD and NASA, and there is strong likelihood that the lack of availability of radiation-tolerant electronics will become a major stumbling block regarding the development of commercial and government-sponsored space communication and surveillance systems within the next few years. Accordingly, it is essential that a strong basis of personnel expertise and testing facilities be maintained in order to address this problem, if the U.S. is to maintain its current lead in space technology. Pertinent technical organizations, including NIST, NASA, universities having relevant research programs, and the appropriate organizations operating radiation facilities, must establish and maintain a close working relationship in order to meet future challenges.

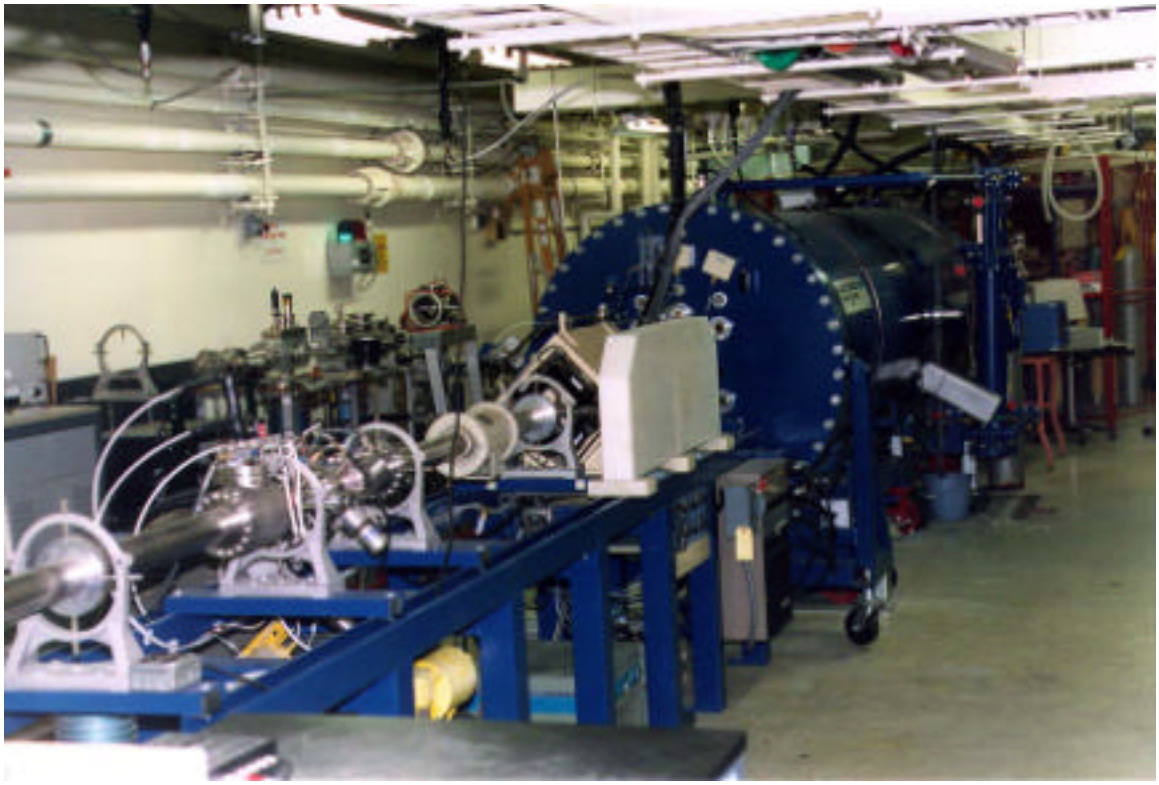
Detailed Program Characteristics

Space radiation environments can be simulated using terrestrial electron, proton and heavy-ion accelerators. In addition, new modeling approaches developed in the last few years have reduced the necessary amount of component testing required; however, there is no substitute for actual device testing in particle beams to calibrate such analytical techniques. Accordingly, the availability of appropriate particle accelerators must be maintained.

It is well established that high-energy protons originating from deep space pose the single greatest threat regarding radiation-induced damage in space-borne electronic

systems. Therefore, the availability of irradiation facilities that can provide appropriate proton energies and dose-rates in a reliable, reproducible and accurately-calibrated manner is extremely important. The 3 MeV tandem NEC PELLETRON accelerator, operated by the Naval Surface Warfare Center / Carderock Division (NSWC / CD), for example, is fully capable of delivering appropriate proton beams tailored in energy and intensity to permit the successful completion of proton irradiation-damage studies.

Another important aspect concerning radiation damage in electronic components is the ability for the analyst to differentiate between effects arising from neutron-induced radiation damage as opposed to those effects originating from γ-ray-induced damage. The NSWC / CD PELLETRON has a beamline capable of generating monoenergetic, fast neutrons using the $^{7}Li(p,n)^{7}Be$ nuclear reaction. This reaction is particularly useful because it can produce a forward-directed, homogeneous flux of fast neutrons that is practically devoid of any γ-ray component relative to the fast-neutron flux density. Such a beam characteristic stands it in sharp contrast to almost any other neutron source. This source is especially useful in investigations aimed at differentiating effects induced by neutron irradiation separate and distinct from the confounding γ-ray-induced response.



D.3.1¾ The PELLETRON acccelerator at the Naval Surface Warfare Center.

Facilities, Staffing, and Funding

The Naval Surface Warfare Center / Carderock Division operates a 3 MeV tandem NEC PELLETRON that has provided neutron beams of appropriate energy (from 2 to 4

MeV), and intensities (from 1 x 10^{12} to 1 x 10^{16} cm^{-2}) vital for testing electronic components used in space-based applications. This facility is located approximately 15 miles from NIST, and while most of its customers for radiation-hardening studies have come from within DoD in the past, there are no restrictions on the kinds of research nor researchers (within the limits of known foreign enemies) that may make use of the accelerator's services. Industrial, non-DoD-governmental, and university scientists have all made use of the accelerator's capabilities in the past. The proximity of this accelerator to well-established research institutions such as NIST, NASA/Goddard Space Flight Center, and Naval Research Laboratory, as well as to universities with strong space-research-oriented programs like Johns Hopkins University and the University of Maryland (both the College Park and Baltimore County campuses) make this a very attractive facility. It is estimated that an effort of at least one-half man-year per year is necessary to establish and maintain the necessary research and development program.

MPD D.4: NEUTRON DOSIMETRY FOR REACTOR PRESSURE VESSEL SURVEILLANCE

Program Summary

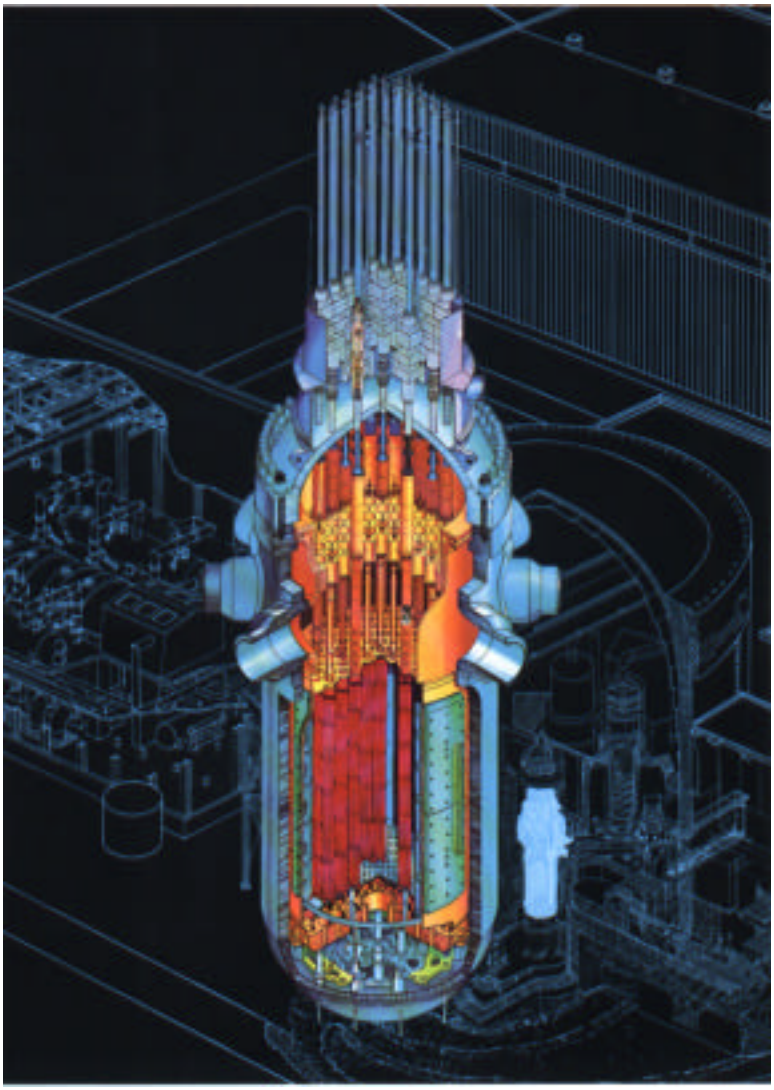
During power operations of light-water-cooled, pressurized water nuclear power reactors, radiation-induced embrittlement will degrade certain mechanical properties important to maintaining the structural integrity of the reactor pressure vessel (RPV). Specifically, fast-neutron (E > 1 MeV) radiation-induced embrittlement of the RPV steel could lead to a compromise of the vessel integrity, under extreme conditions of temperature and pressure, through a reduction in the steel's fracture toughness. This so-called fast-neutron embrittlement is a complex function of many factors including the neutron fluence, the neutron energy spectrum, and the chemical composition of the steel. Additional factors may also come into play, such as the neutron fluence-rate, whose effects have not been fully investigated. Because of the obvious safety implications brought about by a potential breech in the pressure vessel's integrity, the US Nuclear Regulatory Commission (USNRC) has issued requirements designed to help ensure that the structural integrity of the reactor pressure vessel is preserved. In particular, fracture toughness requirements for power reactors, for both normal operating conditions and anticipated operational occurrences, are set forth in Title 10 of the Code of Federal Regulations, Part 50 (10 CFR 50), "*Domestic Licensing of Production and Utilization Facilities*." In order to satisfy the codified fracture toughness requirements, 10 CFR 50 further requires that the operators of all commercial nuclear power stations institute a neutron dosimetry program that provides measurement data for material damage correlations as a function of the fast-neutron fluence.

Accordingly, methods for determining the fast-neutron fluence projected to the end of the license period are necessary to permit a meaningful evaluation of the degree of pressure vessel neutron embrittlement in terms of the neutron exposure. One such method is presented in USNRC Draft Regulatory Guide: DG-1053, "*Calculational and Dosimetry Methods for Determining Pressure Vessel Neutron Fluence,*" which describes techniques and assumptions that are deemed to be acceptable to the NRC staff for determining the pressure vessel neutron fluence. The method described in the guide addresses the calculation and measurement of vessel fluence for pressurized water reactor (PWR) (and to a lesser extent boiling water reactor) designs that are typical of those currently used in the United States. The determination of pressure vessel fluence is based on both calculation and measurements; a prediction of the vessel neutron fluence is made via calculation, and dosimetry measurements are used to qualify the calculational methodology. Such calculations are extremely complex and require detailed knowledge of the plant-specific geometrical and material configuration, as well as the physics describing the detailed behavior of neutrons within the reactor materials. Because of the importance of these calculations and the difficulty in performing them,

qualification of the calculational method by comparing resultant fluence predictions to measurements must be made in order to ensure their accuracy and reliability. Calculation-to-measurement comparisons are also used to identify biases in the calculations, and to provide reliable estimates of the fluence uncertainties.

Detailed Program Characteristics

An essential component of the process promulgated in DG-1053 is the requirement that industrial dosimetry methods be periodically validated , by analyzing measurements of neutron dosimeters irradiated in standard and reference neutron fields. Such fields include the standard ^{235}U fission spectrum at the National Institute of Standards and Technology (NIST), and the reactor leakage spectrum of the Materials Dosimetry Reference Facility (MDRF) located at The University of Michigan's Ford Nuclear Reactor. (The MDRF is maintained jointly by NIST and The University of Michigan.)



D.4.1¾ Cut-away view of a Westinghouse pressurized water reactor.

In order for a measurement method to be validated, the method must be capable of deriving the neutron fluence to which a certified fluence standard has been exposed, within stated accuracy limits. Certified fluence standards are produced by irradiating well-characterized neutron dosimeters in a standardized neutron field; these are then shipped to participating laboratories for subsequent analysis, ultimately resulting in the laboratory's derivation of a value for the neutron fluence. If the derived fluence agrees with the certified value within the experimental uncertainty, then the measurement method / dosimetry system has been validated. If the results do not agree, then the counting techniques and the assay of the dosimeter's material have to be reexamined. If, after, reexamination, a persistent bias is still present, the bias may be used as a detector calibration factor.

The most recent revision to Draft Regulatory Guide 1053 was issued in June 1996, and it is expected that the method endorsed by the Guide will be chosen as the means by which the operators of nuclear power generating stations demonstrate to the NRC their compliance with applicable statutes. Moreover, the American Nuclear Society is presently drafting standard ANS-19.10, *"Fast Neutron Fluence to PWR Reactor Cavities,"* which represents the nuclear industry's consensus standard addressing how RPV neutron fluence determinations should be carried out; the method put forth in the ANS standard mirrors the methodology presented by DG-1053. In general, the analysis of neutron dosimeters from operating U.S. reactors is performed by a small number of industrial metrology laboratories. These laboratories, therefore, constitute the principal customers of periodic, validation irradiations performed at the standard and reference neutron fields.

The need to accurately determine the neutron exposure of inservice reactor vessels is intimately linked to the safe, continued operation of all nuclear generating stations. Thus, it is imperative that this measurement program, which constitutes an integral facet of the overall process by which RPV safety is assessed, be fully implemented and continually supported. In addition, this program can easily accommodate the potential future needs of the operators of foreign nuclear power plants.

Facilities, Staffing, and Funding

The U.S. effort supporting this measurement program is composed of essentially three parts:

1. NIST maintains several standard and reference neutron fields of which four are employed for certified-fluence irradiations related to reactor pressure vessel dosimetry. These fields are a thermal-neutron-induced ^{235}U fission spectrum, a ^{252}Cf spontaneous fission neutron spectrum, the MDRF reactor leakage neutron spectrum, and thermal neutron beams and cavity field. NIST also maintains a supply of well-characterized activation dosimeters, a gamma-ray spectroscopy system, and fission chambers for absolute neutron

fluence measurements. Approximately three man-years per year are committed to this portion of the program.

2. The operational staff at power reactor facilities and the experimental staff at test reactor facilities are responsible for irradiating suitable dosimetry packages (and metallurgical specimens), and for performing appropriate calculations to establish reliable neutron fluence estimates for critical reactor components. The estimated U.S. effort dedicated to this part of the program is approximately 500 man-years per year.

3. Reactor materials dosimetry analysis performed at industrial metrology laboratories currently expends about 50 man-years per year for all of the United States. However, the size of this effort could increase with the adoption of NRC Draft Regulatory Guide 1053, and with the participation/adoption of this program by the operational staff of foreign nuclear electric generating stations.

Progress on MPD D.4.1 Since Publication of 1995 Needs Report

A significant amount of activity under the purview of MPD D.4.1, *Neutron Dosimetry for Reactor Pressure Vessel Surveillance*, has taken place. MPD D.4.1 has been extensively revised to reflect the current state of affairs regarding neutron-induced material embrittlement in reactor pressure vessels. In September 1996, NIST hosted a public meeting in which representatives from the commercial nuclear-electric-generating industry shared their ideas and concerns regarding USNRC draft regulatory guide DG-1053, *Calculational and Dosimetry Methods for Determining Pressure Vessel Neutron Fluence*, with the NRC and the principal authors of the document. Two new ASTM standards addressing the use and application of standard neutron fields, and engineering benchmarks for verification and validation of reactor vessel surveillance analysis, were placed on the books this year. A draft version of a new ANS standard dealing with the determination of RPV neutron fluence is also presently being assembled. Several research endeavors are currently underway. In particular, NIST is conducting an international interlaboratory-comparison of fissionable neptunium dosimeters for use in RPV surveillance monitoring. NIST is also conducting a investigation to assess the adequacy of the ENDF/B-VI iron inelastic scattering cross section for neutrons undergoing deep penetration.

MPD D.5: MEDICAL DEVICE STERILIZATION

Program Summary

The high growth medical device industry relies on a diversity of material constructions to perform unique and sometimes intricate functions. Radiation sterilization has gained increased acceptance as a fast and efficacious means for assuring the microbial quality of such devices. Items as mundane as cotton balls and bandages to sophisticated transdermal drug delivery systems, wound care treatment coverings and complex plastic filtration units are being sterilized by radiation processes. Almost all major producers of medical devices and numerous small companies use irradiation sterilization in their device manufacturing processes.

Many of the measurement and quality assurance procedures required for the safe and efficient sterilization of these medical devices apply to both electron beam and gamma sterilization procedures. Although in the United States the Food and Drug Administration's Center for Devices and Radiological Health does not prescribe a preferred means for attaining sterility, it does require that medical devices be made under current Good Manufacturing Practices (GMP—see "Medical Devices, Current GMP Final Rule; Quality Systems Regulation," Federal Register 61 FR:52602-52662, October 7, 1996, Washington, DC) and in doing so requires a complete protocol of record keeping, traceability, written procedures and the like. For sterilization, the FDA has accepted the standards and guidelines established by the Association for the Advancement of Medical Instrumentation (AAMI—www.aami.org). These along with specific dosimetry test methods and procedures developed by the American Society for Testing and Materials (ASTM—see www.astm.org) provide guidance to the practitioner of radiation sterilization to justify claims of product sterility and to do so within the context of GMP protocols.

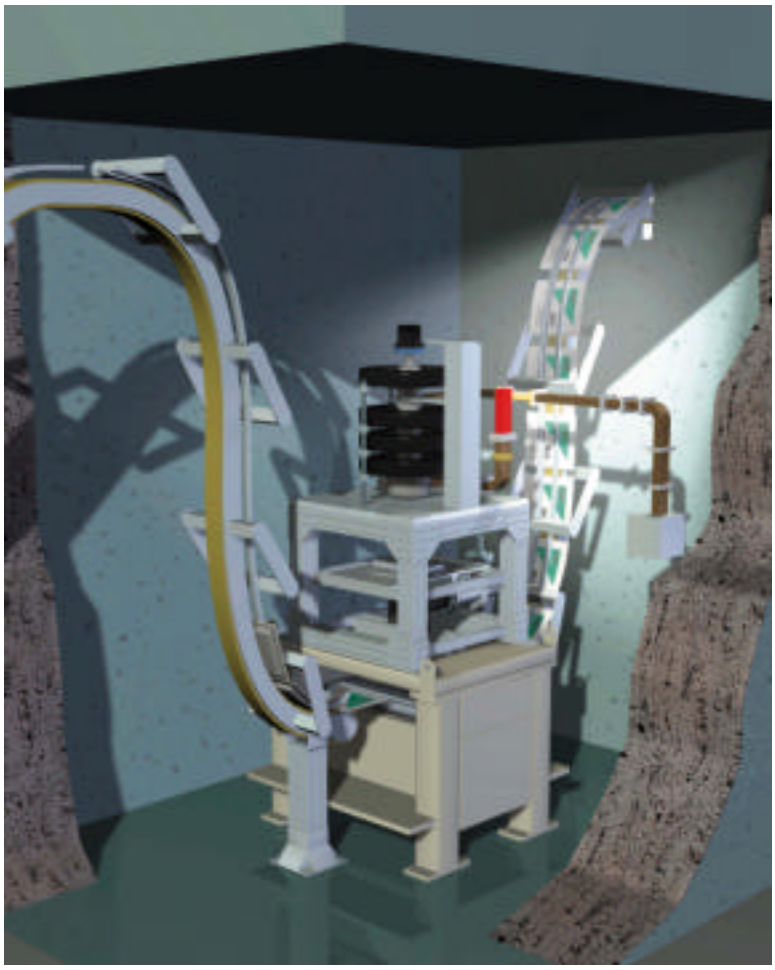
Detailed Program Characteristics

Given the above body of established information on the use of radiation for the steril–ization of medical devices, the CIRMS Industrial Applications and Materials Effects subcommittee focuses on four emerging needs within this measurement community. The need to:

1. Establish cost-effective and timely procedures for NIST calibrations of routine dosimeters.
2. Encourage the use of enhanced dosimetry techniques (e.g. alanine).
3. Establish a national reference beam for high dose rate electron beam output.
4. Foster the development and implementation of Real-Time-Dosimetry methods.

1. Responsive NIST Traceable Calibrations

At the core of FDA cGMP protocols and of the procedures developed by AAMI and ASTM is the requirement to have dosimetry methods traceable to a national standard or reference. While national laboratories like the National Institute of Standards and Technology (NIST) maintains the capability of providing such standards and for performing calibrations, the growth of the medical device industry and its pace have outstripped the capability of NIST to respond in timely fashion to the calibration needs of the industrial community. A proposed solution has been to establish a cooperative program between NIST and an indepen-dent organization which would cofund and provide personnel who could use NIST facilities to perform the necessary dosimetric calibrations.



D.5.1¾ View of a RPC Industries electron beam accelerator for radiation sterilization.

It is estimated that it will take six months of negotiation for NIST to resolve how best and with whom to carry out this needed collaboration. Over the longer term, once a cooperative procedure is in place, at least two-thirds of a year will be required by one person to maintain and quickly respond to the secondary laboratories needs for dosimetric calibrations to the national standards.

2. Enhanced Dosimetric Techniques

A commonly accepted dosimetry technique followed within the medical device industry is to perform dosimetry using either PMMA (polymethylmethacrylate) dosimeters (ASTM E-1276-96) or radiochromic film (ASTM E-1275-93). Pieces of a specially dyed PMMA or thin plastic film containing a radiochromic dye are measured for optical absorbance. Such changes in absorbance are then back correlated with dose to a reference standard. This widely used procedure maintains a precision of approximately

+/- 6% at the 95% confidence level. It has been found that a simple organic molecule, alanine, has excellent dose response over a wide dose range. When admixed in a pellet or film, alanine dosimeters (ASTM E-1607-96) may substantially enhance the precision of dosimetric measurements, having a potential precision of approximately +/- 3% at the 95% confidence level. Given the possible diversity of alanine dosimeter forms, e.g. pellets, powders, thin films, etc., and its requirement for more sophisticated instrumentation, there is a need for industry training and for the establishment of NIST traceable protocols for this more precise dosimetry technique.

It is estimated that it will take a continuing effort of at least one-half person-year over the next three-year period to continue the industry transition to this more precise dosimetry method and to demonstrate its applicability in more diverse product forms.

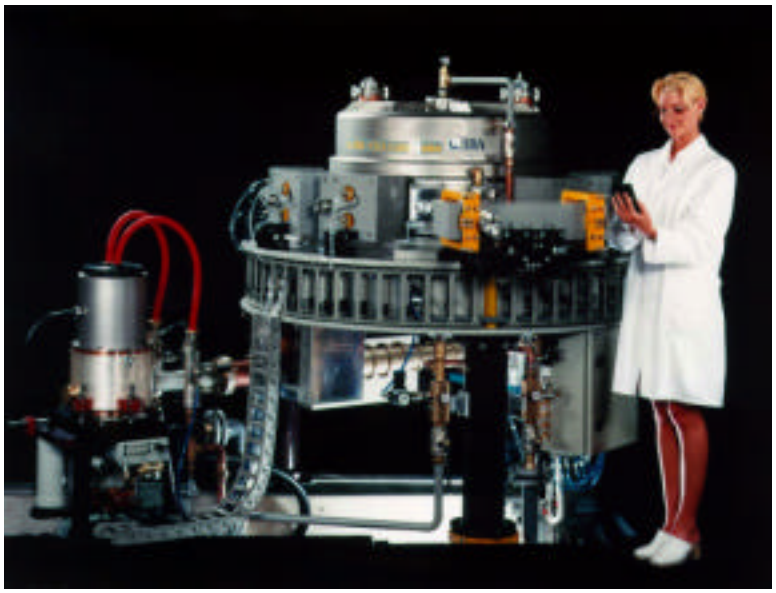
3. High Dose Rate Reference Electron Beam

Depending upon the product form and packaging, high dose rate electron beams are used to sterilize some medical devices. Typically these electron beam accelerators operate at beam currents of between 5 and 50 milliamperes at very high pulse rates or at continuous beam output. As a result, these high current accelerators provide dose rates in the order of 10 kGy or greater per second. Accelerators used for research purposes, some of which have been considered as possible reference beams, operate at much lower beam currents. For example, at the National Physical Laboratory in the United Kingdom, reference beam dose rates of at most 20 kGy per minute or 0.3 kGy per second have been attained. As the option of using high current electron beam accelerators for medical device sterilization gains recognition, the need for a thoroughly calibrated reference beam operating at dose rates encountered in industry becomes apparent. Of some consequence to the medical device industry is that the effects of ionizing radiation on some materials, such as the consequent scissioning of polypropylene, are dose rate dependent, with less deleterious effects being observed at higher dose rates.

To expedite the calibration of a high current reference electron beam accelerator, it is advisable for NIST to collaborate with an industrial or academic partner who already has such an accelerator. It is estimated that it will take one-half person year to complete the needed electron beam calibrations and to establish protocols for use of such electron beam as a NIST qualified reference beam.

4. Real-time Dosimetry

The feasibility of two modalities of real-time dosimetry has been demonstrated for electron beam systems which can be used for medical device sterilization. The “Monitorad” system developed by Trygon, Inc. relies on judicious placement of x-ray detectors near the source of electrons to monitor the delivered dose. The “CDose” system developed by Atomic Energy Canada, Ltd. has been shown to function with high voltage, 10 MeV accelerators and relies upon detection of the electron flux in a segmented beam stop mounted directly in front of the electron source. Both systems



D.5.2¾ View of a Rhodatron electron beam accelerator for radiation sterilization from Ion Beam Applications.

have been correlated with traditional dosimetry methods traceable to NIST. The advantage of real-time dosimetry is that product being sterilized can be continuously monitored and the dose received by each individual increment of product can be logged into a database for traceability purposes. Likewise, electronic process controls can integrate the electron beam parameters of beam current and voltage with product line speed under the beam so that dose can be controlled through slaved feedback mechanisms. Establishment of real-time dose monitoring sterilization systems will reduce the operator dependent measurements of transfer materials, such as the traditional dosimetry films and detection devices, which are read independent of the actual process. There is a need to explore the applicability of these real-time monitoring systems over a broader range of accelerator parameters, that is using a greater diversity of accelerator voltages, as well as to determine the feasibility of using such radiation detection for real time monitoring of gamma processes.

It is estimated that at least one-half person year of effort over an extended period of time is needed within NIST to continue collaboration with industry on the development of this promising technology.

Progress on MPD D.5 (formerly D.1 and D.2) Since Publication of 1995 Needs Report

AAMI has published eight documents pertinent to radiation sterilization and is in the process of publishing additional ones:

- AAMI TIR 17:1997—"Radiation Sterilization Material Qualification"
- AAMI TIR 8:1991—"Microbiological Methods for Gamma Irradiation Steril–ization of Medical Devices"
- AAMI / CD-1 TR 198WG22 (1Nov96)—"Sterilization of Health Care Products—Radiation Sterilization—Variations of ISO Dose Setting Procedures in Relation to the Design of Verification Dose Experiments and Dose Audits"
- AAMI / CDV-1 TR 15844 (1Jun97)—"Sterilization of Health Care Products—Radiation Sterilization—Selection of a Sterilization Dose for a Single Production Batch"
- AAMI / ISO TIR 13409 (1996)—" Sterilization of Health Care Products—Radiation Sterilization—Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Batches"
- AAMI / ISO TR 198WG203:1—" Sterilization of Health Care Products—Radiation Sterilization—Guide to Selection of an Appropriate Method for Establishing a Sterilization Dose"
- ANSI / AAMI ST60 (1996)—"Sterilization of Health Care Products—Chemical Indicators—Part 1: General requirements"
- ANSI / AAMI / ISO 11137 (1994)—Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization"

ASTM, through the efforts of Sub-Committee E10.01 on Dosimetry for Radiation Processing, has published eighteen standards pertinent to radiation sterilization. These deal with the specific details of making dose measurements. ASTM is also in the process of publishing a new "Standard Practice for Blood Irradiation Dosimetry."

- ASTM E 1205-93—"Standard Practice for Use of a Ceric-Cerous Sulfate Dosimetry System"
- ASTM E 1261-94—"Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing"
- ASTM E 1275-93—"Standard Practice for Use of Radiochromic Film Dosimetry System"
- ASTM E 1276-96—"Standard Practice for Use of a Polymethylmethacrylate Dosimetry System"

ASTM E 1310-94—"Standard Practice for Use of a Radiochromic Optical Waveguide Dosimetry System"

ASTM E 1400-95a—"Standard Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory"

ASTM E 1401-96—"Standard Practice for Use of a Dichromate Dosimetry System"

ASTM E 1538-93—"Standard Practice for Use of the Ethanol-Chlorobenzene Dosimetry System"

ASTM E 1539-93—"Standard Guide for Use of Radiation-Sensitive Indicators"

ASTM E 1540-93—"Standard Practice for Use of a Radiochromic Liquid Dosimetry System"

ASTM E 1607-96—"Standard Practice for Use of the Alanine-EPR Dosimetry System"

ASTM E 1608-94—"Standard Practice for Dosimetry in an x-ray (Bremsstrahlung) Facility for Radiation Processing"

ASTM E 1631-96—"Standard Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations"

ASTM E 1649-94—"Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV"

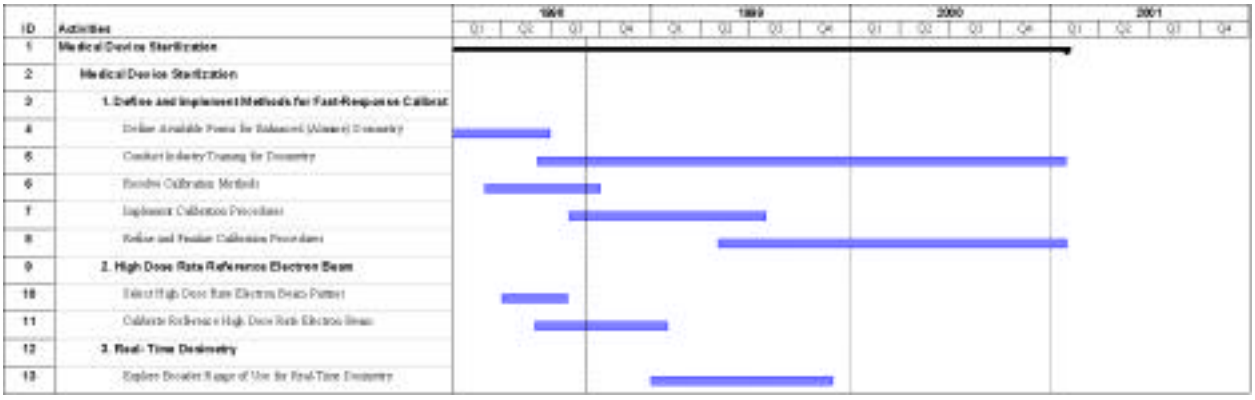
ASTM E 1650-97—"Standard Practice for Use of Cellulose Acetate Dosimetry System"

ASTM E 1702-95—"Standard Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing"

ASTM E 1707-95—"Standard Practice for Estimating Uncertainties in Dosimetry for Radiation Processing"

ASTM E 1818-96—"Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV"

These two organizations along with the FDA are working with the International Organization for Standardization (ISO) to harmonize these existing protocols and procedures with the evolving body of internationally recognized methods for using radiation sterilization and for proper use of dosimetry methods.



D.5.3 – Roadmap for medical device sterilization.

MPD D.6: POLLUTION PREVENTION (P2)

Program Summary

Many uses for ionizing radiation have been demonstrated which can prevent or remediate and thereby eliminate harmful pollutants found in air, water or land. The diversity of these Pollution Prevention (P2) uses is summarized below. In general, ionizing radiation is used to destroy and thus eliminate pollutants found in a variety of industrial environments. Some common themes are found amidst these various uses:

A. Most often, the parameters measured to assure that sufficient radiation exposure has been achieved to eliminate a pollutant, such as the detoxification of halocarbon contaminated water, rely on direct chemical and/or biological measurements of effluents and not on dosimetric, or indirect, measurements.

B. Where most successful, industry has adopted the use of ionizing radiation processes to prevent pollution, as in the use of low voltage electron beam technology to convert or crosslink coatings, inks and adhesives from viscous liquids, which have near zero volatile organic components (no VOCs or solvents) to functional "dried" materials. This eliminates air pollutants from such processes and enables practitioners to comply with the provisions of the Clean Air Act.

C. Even though the technical feasibility and scientific bases for other pollution preventing uses of ionizing radiation have been well understood, where these involve public issues, such as the treatment of wastewater, sewage sludge and stack gases, there has been insufficient public investment in process development to advance the widespread use of ionizing radiation as a P2 process technology.

Elimination of VOCs: Historically, the application of coatings, inks and adhesives and similar materials have relied on the use of solvent vehicles which are driven off during processing to produce final products, such as high gloss magazines, pressure sensitive tapes and labels, printed containers, and the like. Through modification of the chemistry involved in the materials being applied, it is possible to eliminate the volatile organic components (near zero VOCs) and permit conversion of products to their finished form by exposing such innovative materials to low voltage electron beams, 300 keV and below. This results in a process technology which not only eliminates solvent emissions, a common air pollutant, but also enhances product yields and energy conservation. The adoption of this process has made the low voltage segment of the accelerator market the fastest growing portion of this industry, with almost all of the over 300 industrial installations noted being used for these purposes. Such low voltage, self shielded accelerators cost in the neighborhood of $1M, indicating a substantial industrial commitment to this process technology. Major proponents of electron beam use for

pollution prevention in this area are such companies as the 3M Company, International Paper, Tetra-Pak. The combined effect of the industrial acceptance of this electron beam process technology has been to eliminate tens of millions of pounds of undesirable solvent emissions and to reduce the need for less efficient solvent recovery and incineration processes.

Stack Gas Irradiation: The ability to convert undesirable sulfurous and nitrous oxides (SO_2 / NO_x) from the emission of fossil fuel burning systems by exposing such exhausts to ionizing radiation has been demonstrated numerous times. The result is not only clean, uncontaminated air, but also a flocculent precipitate of nitrates and sulfates, which may have use as a soil fertilizer. Demonstrations of this process were conducted by the US Department of Energy in the 1980's at a test facility in Indianapolis, Indiana (N. Frank, et al, Radiation Physics and Chemistry, Vol. 25, Nos. 1-3, pages 35-45, 1985) using two 800 keV electron beam accelerators. Additional studies have been conducted in Japan in collaboration with the Japan Atomic Energy Research Institute in Takasaki involving a good sized pilot facility at the Chubu Electric Company, an incinerator plant and also some mountain tunnel exhaust emissions. In Poland, pilot plant scale facilities with two 700 keV accelerators have been used by the Institute of Nuclear Chemistry and Technology to study the effects of electron beam radiation on emissions from a coal burning system used to produce hot water for district heating. The International Atomic Energy Agency (IAEA) has recently funded ($20M+) a full scale demonstration facility involving two 700 keV high current accelerators to assess the industrial viability of this process for eliminating SO_2 / NO_x from coal fired power plant emissions in Poland on a nearly full scale basis. In the 1990's, an attempt by the US Defense Nuclear Agency to construct a stack gas irradiation facility in northern Virginia failed in part because of the lack of participation by reputable industrial accelerator manufacturers.

Sewage Sludge Treatment: In the 1970's, it was demonstrated that a fluid stream of sewage sludge could be disinfected to eliminate hazardous pathogens by the use of electron beam radiation at the Deer Island Wastewater Treatment Plant in Boston. In 1984, a 1.5 MeV electron beam sewage sludge treatment process was put into operation within the Miami Dade Waste Treatment facility in Florida. This full-scale demonstration facility was plumbed into the sludge and waste treatment network of the waste treatment plant and again showed the efficacy of this process in eliminating bioburdens. Issues involving what to do with the treated sludge and a reticence on the part of municipal water districts to engage in such process changes led to the abandonment of these programs. Scenarios were envisioned in which the treated sludge could be used as disinfected fertilizer for crops. However, to accomplish this in an efficient manner, probably implies locating such demonstration facility more proximate to agricultural land, rather than in urban areas. Although proven and viable, the use of ionizing radiation to treat sewage sludge is no longer being pursued within the United States.

For information on the use of ionizing radiation in the treatment of sludge, wastewater see:

Radiation Energy Treatment of Water, Wastewater and Sludge, 1992
Environmental Engineering Division, American Society of Civil Engineers
345 East 47th Street, New York, NY 10017-2398

Proceedings of a Workshop on Applications of Ionizing Radiation for Decontamination of Environmental Resources, 1994
University of Miami, Post Office Box 248294, Coral Gables, FL 33124-0630

Enhancement of Wastewater and Sludge Treatment by Ionizing Radiation, 1997
University of Miami, Post Office Box 248294, Coral Gables, FL 33124-0630

The latter two references are the proceedings of workshops sponsored by the Directorate for Engineering, Environmental Engineering Division, of the National Science Foundation.

Wastewater Treatment: The use of halogenated organic solvents, such as trichloroethylene and tetrachloroethylene, for metal degreasing, dry cleaning and similar processes along with chlorination processes, such as those used in the bleaching of paper, produces a variety of toxic halo-organic compounds which find their way into effluents and wastewater. These and analogous compounds, such as the polychlorinated biphenyls (PCBs), which had a historic use as additives in transformer coolant and insulating oils, can be dehalogenated, that is decomposed to remove the chorine or other halogens attached to the organic molecule, by exposure to ionizing radiation. Studies conducted by the University of Miami and the Drinking Water Institute of Florida International University using the Miami Dade 1.5 MeV electron beam system have documented exposure levels required to completely detoxify and dehalogenate such undesirable compounds. While the technical feasibility of this approach has been demonstrated using the full scale electron beam treatment of the Miami Dade facility, tighter environmental restrictions on the general use of such halogenated materials has diminished the overall need for this quite viable process. A major use for this technology, however, will remain in the treatment of halo-organic compounds found in the effluent of paper mills, which, because of their locations, generally discharge effluents into relatively pristine fresh water streams and rivers. Even with shifts in technology, in the foreseeable future, not all paper mills will be able to convert to more environmentally friendly bleaching practices.

Ground Water Remediation: Just as undesirable halocarbons have found their way into wastewater systems, they have also been spilled on land and have then seeped into ground water. Because such contaminated sites are not interconnected through sewage lines or natural formations for moving water, innovative transportable electron beam systems have been built which can bring a self-shielded, relatively low voltage (e.g. 500 keV) accelerator to a site with such accelerator housed in a trailer. A transportable beam can remain at a given site until water has been pumped up, processed and returned as

clean water to the ground. Having completed the remediation of one site, the accelerator can then be easily relocated to another site and commence ground water remediation again. High Voltage Environmental Applications and the Raychem Corporation have built demonstration transportable electron beams and proven the technical effectiveness of this approach. A question remains as to the market viability of this technology versus alternative methods for on-site ground water remediation.

Soil and Sediment Remediation: Longer lasting and more hazardous organic compounds, such as polychlorinated dibenzodioxins (dioxin), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) have found their way into soils and sediments. It has been shown that ionizing radiation can also decompose these halocarbons to leave safer by-products. However, because of the nature of soils and sediments, which are fundamentally mixtures of organic and inorganic chemicals, there are competing reactions involving radiation. Thus, there remains a considerable engineering challenge as to how to present such contaminated materials to an ionizing radiation source. Materials transport becomes a major issue. Thus, although technical feasibility has been demonstrated, there has been no scale-up of this process.

Potable Water Purification: Ionizing radiation is known to kill bacteria and other undesirable organic matter, coliforms, etc. Pure potable water can be produced using ionizing radiation in conjunction with selective filtration. A major advantage of this process over historic uses of chlorine and fluorides is that water so treated does not pose a problem of internal corrosion to pipes, pumps and water transport systems. The technical feasibility of this approach has been demonstrated on a small-scale basis, but, again, there has been no scale-up of this process.

Medical Waste Treatment: Significant costs are incurred when transporting biohazards away from hospitals to disposal and incineration facilities. It could become more cost-effective to treat such biohazards, as contaminated dressings, drapes, gowns, etc., at the hospital itself. A medical-waste-treatment demonstration facility has been established at the Jackson Memorial Hospital complex in Miami using a low power, high penetration 8.0 MeV accelerator. Consideration is also being given to whether other radiation sources found in some hospital settings can on off-hours be converted to use of biohazardous waste treatment. Dosimetric protocols in this area will parallel those already established for the sterilization of medical devices.

Detailed Program Characteristics

In order for the proven capabilities of ionizing radiation in the field of pollution prevention (P2) to become adopted and achieve effective use, the CIRMS Industrial Applications and Materials Effects subcommittee points to several significant needs:

1. Knowledge of the effectiveness of these various P2 ionizing radiation processes needs to be more broadly disseminated amongst the engineering community. Even the accepted industrial use of electron beam processing to

eliminate volatile organic emissions from coating and converting processes suffers from a lack of widespread recognition.

2. Engineering studies are needed to optimize the manner in which fluid streams are presented to sources of ionizing radiation in order to maximize process rates.

3. Most radiation P2 processes involve chemical changes in the materials being presented to a source of ionizing radiation, i.e. crosslinking or curing a coating, dehydrohalogenation of toxic compounds, etc. In-line process monitoring needs to be developed in each instance. Since electron beam radiation is generated by an electrical source, the emission of such radiation can be slaved to out-put analysis in order to assure the desired functioning of a P2 process.

4. Substantial capital is needed to foster state-of-the-art demonstration facilities in many of the P2 areas. As noted, the IAEA has funded a demonstration facility for stack gas irradiation in Poland. However, the facility at Miami Dade being used for wastewater treatment studies relies on older equipment and no full-scale demonstration facilities exist for some of the above mentioned processes.

It is estimated that it would take at least six months of project planning effort to adequately delineate the manpower and costs associated with these various needs. A goal in its own right would be a comprehensive plan to implement the diverse and proven uses for ionizing radiation processes in the area of pollution prevention. In the United States, there is a major need for adequate funding of large-scale demonstration facilities. This requires a collaborative effort between Federal, State and local governments and their agencies, engineering firms and accelerator manufacturers with proven industrial capabilities.

MPD D.7: FOOD IRRADIATION

Program Summary

Increased concerns about the overall safety of the food supply chain in North America have, in the United States, empowered the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) with greater inspection authority and the demand for improved methods of detection of contaminants and pathogens in foodstuffs. Outbreaks of foodborne illness resulting from Salmonella and Escherichia coli contamination, especially in red meats, have spurred public support for these measures. Against this background, there is emerging a renewed interest in the use of ionizing radiation as a method to control pathogens in food products. (See http://www.food-irradiation.com/ for technical details.)

The efficacy, minimal effect on nutritive value and general safety of irradiating food has been demonstrated over and over again throughout the past three decades. The World Health Organization has long been on record as supportive of this method for treating food. However, in North America, there has been little practice of this proven method for enhancing the safety of foodstuffs. While several providers of contract gamma radiation services treat spices in bulk quantities which are then used in the preparation of a variety of food products, there is only one commercial source whose primary business is the irradiation of food products: Food Technology Services, Inc. of Mulberry, Florida. Despite considerable misconceptions about consumer reactions, Food Technology Services has had generally favorable response to its irradiated produce, providing safe and less perishable items to up-scale suburban stores, where in fact consumers have shown a preference for irradiated food products, clearly designated as such by an internationally agreed upon labeling. The reticence to accept this well proven process seems to be more on the part of major providers of food products than on the part of an informed public.

While research into the effects of ionizing radiation had long been conducted at the US Army's Natick, Massachusetts, laboratories, targeted programs involving food irradiation in North America are now mainly being conducted at the Canadian Irradiation Centre (Ville de Laval, Quebec) which operates in cooperation with the Universite du Quebec, Institut Armand-Frappier, at the Canadian Department of Agriculture's Food Research Centre (St. Hyacinthe, Quebec) and at Kansas State University (Manhattan, Kansas), all involving ^{60}Co gamma irradiation and at a 10 MeV electron beam center at Iowa State University (Ames, Iowa).

Two sub-committees of the American Society for Testing and Materials (ASTM), Sub-Committee E10.01 on Dosimetry for Radiation Processing and Subcommittee F02.40 on Food Processing and Packaging, have developed consensus standards that deal specifically with issues related to food irradiation. Regulatory agencies, such as FDA

and USDA, use those standards in their regulations to assure that good manufacturing practices are followed by plants operating under their inspection. At present, there are eight ASTM standards providing information about food irradiation:

ASTM E 1204-93—"Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing"

ASTM E 1261-94—"Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing"

ASTM E 1431-91—"Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing" ASTM E 1900-97—"Standard Guide for Dosimetry in Radiation Research on Food and Agricultural Products"

ASTM F 1355-93—"Standard Guide for Irradiation of Fresh Fruits for Disinfestation as a Quarantine Treatment"

ASTM F 1356-93—"Standard Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry (to Control Pathogens)"

ASTM F 1640-95—"Standard Guide for Packaging Materials for Foods to be Irradiated"

ASTM F 1736 -96—"Standard Guide for the Irradiation of Finfish and Shellfish to Control Pathogens and Spoilage Microorganisms"

The absorbed doses or D_{10}-values of ionizing radiation needed to destroy one log of colony forming units (cfu) of specific microorganisms which plague the food industry have been well established. For example, the D_{10}-value for *E. coli* O157:H7 in beef is 0.3 kilogray (kGy), which implies that a dose of 1.5 kGy would destroy 5 log cfu of this microorganism. At a dose of 2.0 kGy, it has been shown that this microorganism is virtually eliminated in all forms of beef. The FDA (59CFR, pages 43848-9) has approved a maximum absorbed dose of 4.5 kGy for fresh red meat products which, assuming a 3:1 maximum to minimum dose ratio for radiation penetration, results in a minimum of 1.5 kGy exposure. It has also been shown that at the irradiation doses required for pathogen control, there is virtually no effect on the macronutrients (proteins, fats, and carbohydrates) in meats and that micronutrients (vitamins and minerals) are affected to about the same degree as they are when treated with other processes. At a maximum absorbed dose of 2.0 kGy, Vibrio species and the Hepatitis A virus are eliminated in oysters while not harming the live shellstock oysters. The FDA (see: www.fda.gov) lists a maximum absorbed dose of 1.0 kGy for irradiating fruits and vegetables to delay senescence and control arthropod pests and a maximum absorbed dose of 30 kGy for spice irradiation. Poultry can be irradiated to a maximum absorbed dose of 3 kGy.

Beyond the control of pathogens, it has also been shown that the irradiation process can actually extend the shelf life of certain foods with a minimum loss of nutrient value. Given the diversity of foodstuffs available to the consumer, issues of safety and the elimination of pathogens have taken precedence over such added benefits as shelf-life

extension. Food taste and appearance issues have also remained of secondary importance to improving the safety of the food supply.

Detailed Program Characteristics

Given the complex and multiple issues involved in food irradiation, the CIRMS Industrial Applications and Materials Effects subcommittee has highlighted three needs within this measurement community. The need to:

1. To establish NIST traceable protocols using enhanced dosimetry techniques in the lower dose ranges, i.e. as low as 0.1 kGy, demanded in the food irradiation process.

2. Verify depth-dose relationships in materials which represent the broad spectrum of material densities encountered in food products, e.g. tissue, bone, shell, etc.

3. Examine the potential for x-ray conversion at 7.5 and at 10 MeV using alternative target materials for electron sources and conduct facilities design studies to provide practical guidelines on how to implement x-ray or bremsstrahlung irradiation in food processing.

1. NIST Traceable Enhanced Dosimetry

In food irradiation, FDA and USDA approvals stipulate dose exposure within precise limits and often at relatively low dose ranges for industrial processing, e.g. 1.0 kGy. Both traditional radiochromatic dosimetry films and the evolving use of alanine dosimetry need to be reexamined within these prescribed dosimetry limits and ranges to assure that irradiated foodstuffs indeed meet these regulatory requirements. Likewise as food irradiation becomes an adopted process, there will be increased need to explain the protocols involving dosimetry traceability to a national standard to practitioners involved in the food industry.

It is estimated that it will take a continuing effort of at least one-half person-year over the next three-year period in order to adequately serve this emerging demand in the area of food irradiation.

2. Verification of Depth-Dose Relationships for Food Products

Food irradiation procedures spell out minimum and maximum dose exposure and do so for a variety of different foodstuffs. Because of this diversity of foods, some of which have already been approved for irradiation and others of which are of interest, it is of paramount importance to understand the depth of penetration of either gamma, electron or x-ray (bremsstrahlung) forms of ionizing radiation. The food processing industry will need to understand the limitations of penetration in order to deal with the packaging and the presentation of foods to a radiation source. Ground beef, for example, could be

irradiated in containers using gamma sources, whereas preformed patties could be more readily processed under electron beams. The influence of shells and bone structures on dose penetration also must be studied.

It is estimated that an effort of at least one-person per year over a three year period will be needed to develop sufficient information and prepare a database so that food processors can readily adopt irradiation without the encumbrance of needing to understand dose penetration limits.

3. X Ray Conversion from Electron Beams

It is well known that bremsstrahlung or x-rays generated by the impingement of electron beams on metallic targets can enhance the depth of penetration of electrically generated radiation. Heretofore international protocols for x- ray conversion have limited beam energies to 5.0 MeV. However, since the efficiency of x-ray conversion improves with increasing beam energy, the use of higher beam energies, say 7.5 MeV and 10.0 MeV, could prove more useful to the food processing industry. Accelerators with relevant beam currents at these energies are available which can be used with different target metals for x-ray conversion. Economic analyses need to be reviewed in view of these developments. In addition, food product handling and how it interfaces with the characteristics of a bremsstrahlung source is an engineering challenge that needs to be addressed.

It is estimated that a three person-year effort is needed to adequately reassess both the economic and engineering challenges and opportunities resulting from the laboratory defined advantages of using electrically generated bremsstrahlung or x-rays for food irradiation.

APPENDIX A:
EXAMPLE OF A SUCCESSFUL MPD

MPD A.1: NATIONAL AIR-KERMA STANDARDS FOR MAMMOGRAPHY

Program Summary

In 1992, the U.S. Congress passed Public Law 102-530, the Mammography Quality Standards Act of 1992. This Act requires that all screening and diagnostic mammographic facilities be certified by the Secretary of the Department of Health and Human Services by October 1, 1994. This certification process will involve accreditation by an approved nonprofit private organization or approved State organization. There must be a yearly on-site evaluation by a credentialed medical physicist and a yearly inspection by a credentialed government inspector.

Detailed Program Characteristics

Mammographic units used in the United States commonly use molybdenum for both the x-ray tube anode material and the additional filter used to remove unwanted low-energy bremsstrahlung x rays that contribute to patient dose but not significantly to image quality. One problem in calibrating instruments used to measure the air-kerma rate from mammographic units is that the National Institute of Standards and Technology (NIST) presently does not yet have a national standard for those mammographic beams. In fact, the only national standards laboratory in the world having appropriate national standards is the Physikalisch-Technische Bundesanstalt (PTB), the German standards laboratory. All the reference x-ray beams at NIST are produced by tungsten-anode x-ray tubes. The spectra (and therefore any measure of beam quality) are quite different for these two anode materials. For a tungsten target, aluminum filter system operated at voltages appropriate for mammography, most of the dose results from the thick-target tungsten bremsstrahlung (i.e., low energy x rays), although the L-fluorescent tungsten x rays are present. For a molybdenum target, molybdenum filter system, the K-fluorescent x rays dominate the spectra and there is very little thick-target molybdenum bremsstrahlung. For a reasonable choice of operating voltages, one can match either the half-value layer or the homogeneity coefficient but not both beam quality parameters for molybdenum anodes.

In the United States, the Food and Drug Administration's Center for Devices and Radiological Health (CDRH) is responsible for calibrating all the instruments that the government inspectors will use during the yearly inspection of each mammography facility. The

CDRH X-ray Calibration Laboratory is accredited by NIST's National Voluntary Laboratory Accreditation Program. CDRH is establishing a new facility within the Mammography Calibration Laboratory explicitly to calibrate instruments in appropriate x-ray beams. Since there are no suitable national standards in the United States, CDRH has opted to send its reference ionization chamber to PTB to establish traceability to a national standard.

To perform the annual on-site evaluation, the medical physicists will presumably have their instruments calibrated at one of the American Association of Physicists in Medicine's (AAPM) Accredited Dosimetry Calibration Laboratories (ADCL). One of these laboratories, at the University of Wisconsin, is developing a free-air chamber to measure air kerma from their mammography x-ray units. In principle, the free-air chamber is an absolute device, but in practice it is necessary to determine a number of correction factors. Preliminary comparisons of this chamber with NIST standards have been made in tungsten-anode beams, and measurements of selected mammography chamber response have been made in the molybdenum and rhodium beams at CDRH.

To be able to provide national standards for all secondary laboratories wishing to calibrate mammography probes, it is desirable for NIST to develop suitable reference x-ray beams. An Interagency Agreement has been established with the Food and Drug Administration to develop these national standards. At a minimum, these new reference beams should be identical to the beams recommended by the International Electrotechnical Commission for measuring the characteristics of diagnostic x-ray equipment and for verifying the performance requirements of ionization chambers and semiconductors used in medical radiography.

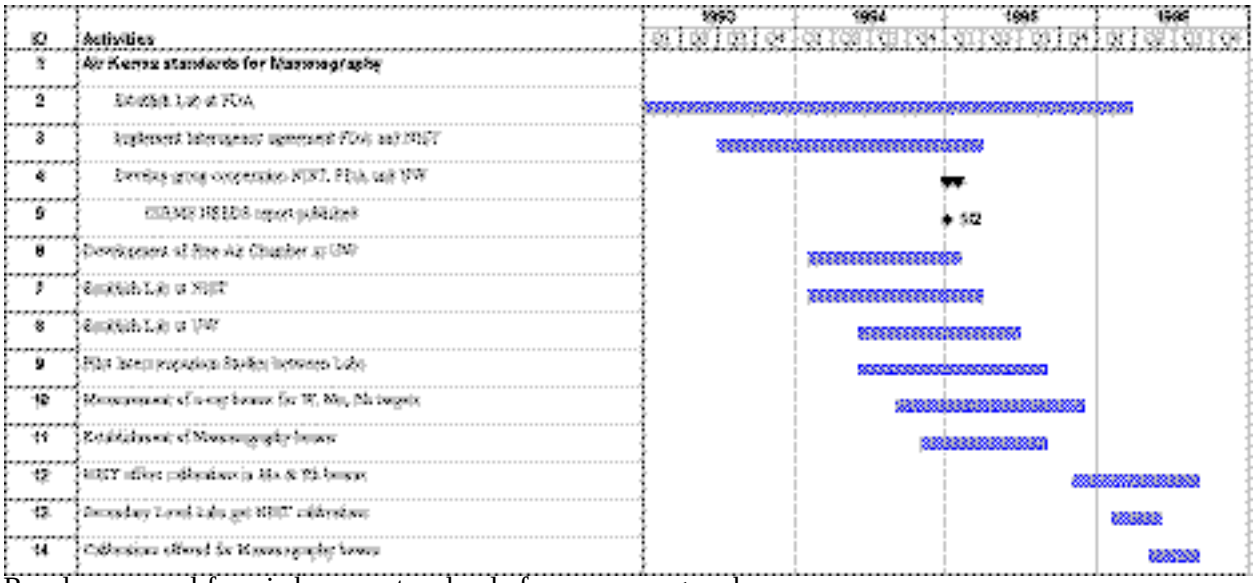
U.S. Facilities, Staffing, and Funding

The appropriate U.S. facilities can be organized into three groups:

1. NIST: As indicated above, NIST needs major new resources in equipment and personnel to carry out this program. With the tight deadlines of MQSA, this program needs high priority. A minimum requirement is 2 person-years and $250,000 for each of two years.

2. CDRH: Most equipment for the new mammography facility has been ordered. Two additional person-years will be required: one to finish developing the automated computer system and the other to do routine calibrations, maintain in-house quality control, and maintain inventory. Equipment costs are estimated to be about $130,000 for each of two years.

3. ADCLs: To set up laboratories for calibrating instruments to measure air kerma from mammography units, it is estimated that each ADCL will need at least $100,000 for equipment and a person to operate the calibration facility. Two of the ADCLs have expressed an interest in developing mammography calibration facilities.



Roadmap used for air kerma standards for mammography.

APPENDIX B:
ACRONYMS USED IN THIS REPORT

The acronyms used in this report are as follows:

AAMI—Association for the Advancement of Medical Instrumentation

AAPM—American Association of Physicists in Medicine

ADCL—Accredited Dosimetry Calibration Laboratory

AECL—Atomic Energy of Canada Limited

ALARA—As Low As Reasonably Achievable

AML—Acute Myeloid Leukemia

ANSI—American National Standards Institute

ASTM—American Society for Testing and Materials

BOMAB—Bottle Manikin Absorption (Phantom)

BRMD—Bureau of Radiation and Medical Devices

CCD—Charge Coupled Device

CDRH—Center for Devices and Radiological Health

CEC—Commission of the European Communities

CERN—Centre European de Recherche Nucleaire

CIRMS—Council on Ionizing Radiation Measurements and Standards

CRADA—Cooperative Research and Development Agreement

CRCPD—Conference of Radiation Control Program Directors

DOC—Department of Commerce

DOD—Department of Defense

DOE—Department of Energy

DOELAP—Department of Energy Laboratory Accreditation Program

DOI—Department of the Interior

ED—Electronic Dosimeter

EML—Environmental Measurements Laboratory

EPA—Environmental Protection Agency

EPR—Electron Paramagnetic Resonance

FDA—Food and Drug Administration

FEMA—Federal Emergency Management Agency

FTE—Full Time Employee

GAO—General Accounting Office

GCRS—Ground Contamination Removal Systems

HPS—Health Physics Society

HPSSC—Health Physics Society Standards Committee

IAEA—International Atomic Energy Agency

IAME—Industrial Applications and Materials Effects

ICRP—International Commission on Radiological Protection

ICRU—International Commission on Radiation Units and Measurements

IEC—International Electrotechnical Commission

INEL—Idaho National Engineering Laboratory

ISO—International Organization for Standardization

LANL—Los Alamos National Laboratory

LED—Light-Emitting Diode

LLNL—Lawrence Livermore National Laboratory

LS—Liquid Scintillation

MAP—Measurement Assurance Program

MAPEP—Multi-Agency Proficiency-Evaluation Program

MARLAP—Multi-Agency Radiochemistry Laboratory Analytical Procedures

MARSSIM—Multi-Agency Radiation Survey and Site Investigation

MDL—Minimum Detectable Limits

MDRF—Materials Dosimetry Reference Facility

MIRF—Medical-Industrial Radiation Facility

MPD—Measurement Program Description

MQA—Measurement Quality Assurance

MQSA—Mammography Quality Standards Act

MRI—Magnetic Resonance Imaging

NASA—National Aeronautics and Space Administration

NCRP—National Council on Radiation Protection and Measurements

NDA—Nondestructive Analysis

NDA—New Drug Applications

NEI—Nuclear Energy Institute

NIST—National Institute of Standards and Technology

NMR—Nuclear Magnetic Resonance

NMS—Natural Matrix Standard

NPL—National Physical Laboratory (U.K.)

NRC—Nuclear Regulatory Commission

NRC-Ottawa—National Research Council

NSWC—Naval Surface Weapons Center

NVLAP—National Voluntary Laboratory Accreditation Program

ORNL—Oak Ridge National Laboratory

PCB—Polychlorinated Biphenyls

PCDF—Polychlorinated Dibenzofurans

PE—Performance Evaluation

PET—Positron Emission Tomography

PMMA—Polymethyl Methacrylate

PNL/PNNL—Pacific Northwest National Laboratory

PPT—Part Per Trillion

PTB—Physikalisch-Technische Bundesanstalt (Germany)

PWR—Pressurized Water Reactor

P2—Pollution Prevention

RESL—Radiological and Environmental Sciences Laboratory

RIMS—Resonance Ionization Mass Spectrometry

RPV—Reactor Pressure Vessel

SPECT—Single Photon Emission Computed Tomography

SRM—Standard Reference Material

TLD—Thermoluminescent Dosimeter

TRU—Transuranics

TWRS—Tank Waste Remediation Systems

UV—Ultraviolet

USDA—United States Department of Agriculture

VA—Veterans Administration

VOC—Volatile Organic Compounds

WAFAC—Wide-Angle-Free-Air-Chamber

WIPP—Waste Isolation Pilot Plant