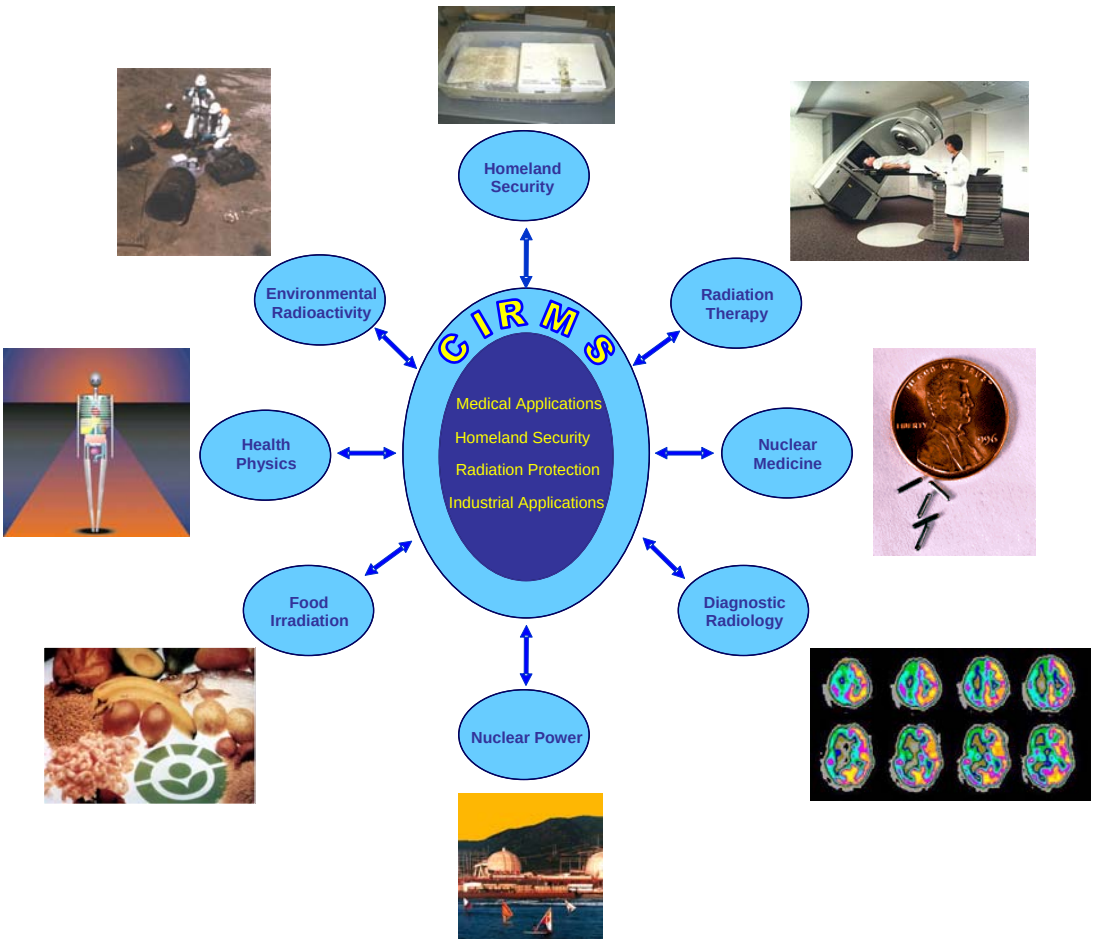
Council on Ionizing Radiation Measurements and Standards



Fourth Report on Needs in Ionizing Radiation Measurements and Standards

Prepared by the CIRMS Science and Technology Committee

December 2004

The Council on Ionizing Radiation Measurements and Standards

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Cover: CIRMS graphics supplemented by pictures representing diverse areas of interest.

Executive Summary

The Council on Ionizing Radiation Measurements and Standards (CIRMS) is an independent, non-profit council that draws together experts involved in all aspects of ionizing radiation to discuss, review and assess developments and needs in this field. Drawing upon expertise from government and national laboratories, agencies and departments, from the academic community and from industry, CIRMS now issues its fourth triennial report on "Needs in Ionizing Radiation Measurements and Standards." Such needs are delineated in Measurement Program Descriptions (MPDs) that indicate the objective, state background information, define needed action items and resource requirements in terms of personnel and facilities.

Each of the subcommittees of the CIRMS Science and Technology Committee has prepared a series of MPDs pertinent to their area of expertise. These were arrived at through dialog at CIRMS meetings and workshops.

CIRMS Medical Subcommittee, which deals with diagnostic and therapeutic uses of ionizing radiation, has found need in four specific areas:

- Radioactivity Standards and Techniques for Nuclear Medicine
- Dose Mapping Systems for 3D Conformal Radiation Therapy and Intensity Modulated Radiation Therapy
- Absorbed Dose Standards for Brachytherapy Sources
- Liquid Based and Micro-Brachytherapy Sources

These reflect current developments in medicine that have come to rely more heavily on the use of radioactive species for diagnostic purposes and treatment. Brachytherapy, for example, is becoming more widely used as an option to treat prostate cancer. Prior to any such internal or to external treatment of cancer, patient dose mapping is needed so that the physician can best treat the targeted or intended area.

The CIRMS Public and Environmental Radiation Protection Subcommittee (PERP), which dealt with radioactivity found in the environment and its possible public health effects, and Occupational Radiation Protection Subcommittee (ORP), which dealt with worker protection in radioactive environments, have been merged into a joint Radiation Protection Subcommittee (RP). Many activities espoused by PERP were evolving into areas of interest for ORP as well. A new subcommittee devoted to the interests in Homeland Security has been formed. Its interests are combined with those in Radiation Protection. Nine Measurement Program Descriptions are defined in these areas:

- Traceability to NIST for Reference, Monitoring and Service Laboratories
- Sorption of Radioactive Elements in Contaminated Soils and Sediments and Urban Structural and Other Materials

- Atom-Counting Measurement Techniques for Environmental and Radiobioassay Monitoring
- Intercomparison Transfer Standards for Neutron Source Calibrations
- Improvements for *In–vivo* and *In-vitro* Radiobioassay Metrology
- Improved Radiation Measurement Infrastructure for Occupational Radiation Protection
- Extension of Calibration Accreditation Criteria to Low Dose Radiations
- Implementation of Support for Personnel Dosimetry Proficiency Testing per ANSI N13.11
- Emergency Radiological Response

These reflect continuing needs to improve upon ways to measure radioactivity, especially in soils, structures and other materials that have been contaminated by hosting activities related to nuclear weapons development. Accurate measurements that will be traceable to national reference standards must be sustained and an understanding of how such radioactivity decays over time is a continuing area of inquiry. Issues of calibration, proficiency testing and the maintenance of a network to monitor dose exposure in occupational settings are covered. The need for a national network capable of responding in the event of terrorist activities involving radiological materials is also addressed.

The CIRMS Industrial Applications and Materials Effects subcommittee (IAME) covers a diverse area generally not related directly to human radiation exposure. In this context, IAME has found need for measurement programs in five areas:

- Radiation Hardness Testing and Mixed-Field Radiation Effects
- Neutron Dosimetry for Reactor Pressure Vessel Surveillance
- Medical Device Sterilization
- Food Irradiation
- Low-Voltage Electron Beam Dosimetry

Terrestrial measurements of the effects (hardening) of types of radiation found in space on electronic materials are essential to satellite operations and communications systems. As nuclear power plants age, radiation effects on their pressure vessels must continue to be monitored. The growing use of irradiation to sterilize medical devices and the emergence of food irradiation demand heightened attention to dosimetry measurements and their traceability to national reference sources.

In an era of constrained government resources, the above point to areas warranting program attention as determined by a consensus of experts from industry, academia and government laboratories and agencies. Adequate resources should be allocated so that the objectives outlined in each area can be accomplished.

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Preface

This is the fourth triennial issuance of a "Needs Report" by the Council on Ionizing Radiation Measurements and Standards (CIRMS). CIRMS is an independent, non-profit council that draws together experts involved in all aspects of ionizing radiation to discuss, review and assess developments and needs in this field. CIRMS membership is drawn from government agencies and departments, the academic community, industry and individuals skilled in the scientific and technical demands involving ionizing radiation. (Appendix A presents the history and origins of CIRMS and its methods of operation, means of communication and structure.)

CIRMS brings these constituents together through its annual meetings and through focused workshops. Information on these is then posted on the CIRMS web site: www.cirms.org. Through dialog in these open forums, the members of CIRMS arrive at an advisory agenda on the needs for measurements and standards in ionizing radiation. Critical issues warranting expert attention are put forth as Measurement Program Descriptions (MPDs – see following section).

Having been launched as a coordinating council with a primary objective of providing guidance to the Ionizing Radiation Division at the National Institute of Standards and Technology (NIST), CIRMS role has grown to include activities involving other national laboratories and the international standards community. Three non-US laboratories are organizational sponsors of CIRMS: the Austrian Research Centre in Seibersdorf, the National Physical Laboratory (NPL) in the United Kingdom, and the Physikalisch-Technische Bundesanstalt (PTB) in Germany. In addition, representatives from the Canadian National Research Council, the Risø National Laboratory in Denmark and from the International Atomic Energy Agency (IAEA) have addressed CIRMS members at workshops and annual meetings. In some areas, such as in the sterilization of medical devices and food irradiation, consensus standards developed through ASTM International (ASTM) have been accepted by the International Standards Organization (ISO). CIRMS and its individual members interact with a number of professional and industrial associations. There is outstanding cooperation with the American Association of Physicists in Medicine (AAPM), which is an organizational sponsor, with the Health Physics Society (HPS), and with the American National Standards Institute (ANSI).

Government agencies and departments too have been supportive of CIRMS and their representatives have been involved in establishing the needs spelled out in this report.

Of particular note has been the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), some groups within the Department of Energy (DOE), particularly those concerned with personnel and environmental radiation safety, the Nuclear Regulatory Commission (NRC), and the Army Primary Standards Laboratory. Some of the DOE national laboratories, such as Los Alamos National Laboratory (LANL), Oak Ridge National Laboratory (ORNL) and the Pacific Northwest National Laboratory (PNNL) also have members engaged in CIRMS activities. Many of these have also become organizational members of CIRMS.

CIRMS also benefits from individual contributions from members of the academic community, such as members on the staff at the University of Wisconsin, at Rensselaer Polytechnic Institute, at the University of Texas M. D. Anderson Cancer Center, and at the University of Maryland. Kent State University, the radiation laboratory at the University of Notre Dame and the Neely Nuclear Research Center of Georgia Institute of Technology have become organizational members of CIRMS. US industry has acknowledged the benefits of the openness and dialog within CIRMS and provided growing support (see the inside cover for a listing of CIRMS corporate sponsors). While the list of CIRMS organizational and corporate supporters has more than doubled in the past several years, clearly there are many more academic institutions, organizations and government entities that would benefit from participation in the open forums assembled by CIRMS.

In this fourth "Needs Report," there are several key changes from the prior three editions ("Needs Report – I" of January 1985, "Needs Report – II" of October 1998, and "Needs Report III of October 2001 – all of which can be linked into on the CIRMS web site: www.cirms.org). The initial CIRMS "Needs Report" defined 22 Measurement Program Descriptions (MPDs) in the four areas of technical interest within CIRMS. In the second edition, some of these same expressed needs were revised and continued and new ones introduced, thus, presenting an agenda of 23 MPDs. The third edition was more focused, targeting fewer MPDs and only 16 areas of interest. This did not represent a diminished demand for needed activities in measurements and standards for ionizing radiation, but reflects the realities of attempting to achieve more with fewer and more constrained available resources. The CIRMS Science and Technology committee would prefer to define programs that can actually be accomplished than list measurement needs that have little chance of being met in the foreseeable future. CIRMS is an independent expert advisory council, and not itself directly engaged in the allotment of resources.

The notable changes in this fourth edition are:

1) Dropping of the term "National" from the title to reflect the aforementioned international participation in CIRMS and the international involvement in ionizing radiation standards in general.

2) The reorganization of the subcommittee structure which combined the former Public and Environmental Radiation Protection (PERP) and the Occupational Radiation Protection (ORP) subcommittees into one, the Radiation Protection subcommittee (RP).

3) The creation of a new subcommittee focused on the measurement needs in Homeland Security (HS). The needs in this emerging area have been for now melded into those in the Radiation Protection area. (Section B/C/E.)

4) The inclusion of a new section on the pervasive area of Computational methods. Modeling and computational techniques underlie many areas of radiation use, ranging from planning for treatment therapy to the analysis of packages to be sanitized for the US Postal Service.

5) Noting of two additional areas of CIRMS impact via a letter of commendation from the Director of NIST and citing the involvement of CIRMS leadership in endorsing the successful use of ionizing radiation to sanitize the mail. (Appendix B-1 and Appendix B-3.)

In this edition, there are 19 MPDs. A new MPD has been added to the Medical section to cover more recent developments in brachytherapy (MPD A.8.0). Within Radiation Protection, there are three new MPDs devoted to interests in Homeland Security (MPD E.1.0, E.2.0 and E.3.0). In the Industrial Applications and Materials Effects (IAME) area, a new MPD has been created to deal with the calibration issues involved with low-voltage electron beams (MPD D.8.0). An MPD has been developed to express needs in the Computational area (MPD F.1.0). Other MPDs have been revised and brought up-to-date, with some being dropped in that the work in an area has been completed and the objectives met.

Within the context of each of the MPDs in this report, one will find emphasis on collaboration amongst various organizations. The MPD format states each program's objective, provides background information pertinent to the measurement or standardization need, outline some action items needed to meet said objective, and provides an estimate of the resources needed to accomplish such tasks.

While CIRMS is extremely broad in its scope and areas of interest, clearly there are many activities involving ionizing radiation that have yet to take advantage of participation in the open forum and peer discussion provided by CIRMS. It is hoped that agencies, departments, academic institutions, professional and industrial organizations and knowledgeable individuals will take advantage of this and join in the council's activities and deliberations.

Reviewed and submitted by:

CIRMS Executive Committee and Science and Technology Committee

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Acknowledgement:

Katy Nardi, CIRMS Executive Secretary, for the preparation and reproduction of this report.

Introduction

CIRMS Mission and Vision

CIRMS Vision Statement

CIRMS is an independent proactive forum that provides leadership, focus, action, and information dissemination across all aspects of all irradiation disciplines involving a wide range of ionizing radiation measurements and standards topics.

CIRMS is *THE* council that speaks for the ionizing radiation measurements and standards community and works with national and international standards groups to bring consensus, consistency, and commonality in applications involving industry, academia, the medical community, and government needs.

CIRMS Objectives

- CIRMS is an open FORUM for discussion
- CIRMS seeks to stimulate COLLABORATION amongst:
  Government
  Industry
  Academia
- CIRMS gathers information and then ARTICULATES NEEDS
- CIRMS facilitates PRIORITIZATION of needed work
- CIRMS RECOMMENDS ACTION steps
- CIRMS provides INFORMATION to NIST and other national laboratories in order to promote better, more consistent standards
- CIRMS attempts to provide the SECONDARY LABORATORIES with information and data that will strengthen their capabilities
- CIRMS DISSEMINATES INFORMATION on STANDARDS through its web site: www.cirms.org
- CIRMS holds WORKSHOPS in order to bring specific issues into greater focus
- CIRMS holds annual MEETINGS that challenge its vision

Goals

- Provide a FORUM for the inter-disciplinary exchange (drawn from government, academic, and industrial constituency) of information on ionizing radiation measurements and standards topics.

- Gather INFORMATION, analyze, and build consensus and prioritize information on ionizing radiation measurements and standards.

- Seek to HARMONIZE standards through selection, avoidance of duplication, mutual recognition, verification and comparability.

- Disseminate, coordinate, and RECOMMEND actions on ionizing radiation measurements and standards.

How does CIRMS serve as a forum?

- Through CIRMS annual meetings
- By outreach to national and international organizations
- By dialog with regulators and policy-makers
- Through focused subcommittees
- Through interagency coordination
- By challenging proactive members in cross-cutting disciplines / agencies / industries
- Through teleconferencing processes and use of the Internet

How does CIRMS disseminate information?

- CIRMS Needs Reports
- CIRMS web page and interactive e-mail
- Improved international communications

CIRMS Strategies

- Establish an outside and a champion within the NIST Ionizing Radiation Division for each Measurement Program Description (MPD)
- Determine key interface point-of-contacts for CIRMS
- Determine the resources needed to implement a given MPD
- Determine facilitator roles and choose active facilitators to achieve goals
- Provide fact sheets on major areas
- Establish needed interactions with other organizations involved in ionizing radiation, especially those involved in standards and measurements
- Maintain dialog with the international standards community
- Determine areas of deficiencies and recommend needed actions

Mission Areas for CIRMS

Diagnostic Radiology

Radiation Therapy

Nuclear Medicine

Environmental Radioactivity

Health Physics

Radiation Sterilization

Nuclear Electric Power

Radiation Processing

Homeland Security

MEASUREMENT PROGRAM DESCRIPTIONS

Needs in ionizing radiation measurements and standards are presented in a format called a "Measurement Program Description" or MPD, which has four components:

Objective: In very concise terms, a statement of what the program is to achieve.

Background: What was presented as the "Program Summary" and "Detailed Program Characteristics" in the first two "Needs Reports" was melded into one section detailing pertinent information about the program, needed prior information, current activities and reasons for pursuing these objectives, as had been done in the previous report.

Action Items: Each MPD lists specific tasks or action items that should be completed in order for the measurement program to meet its objectives. These can provide a means for determining the progress and success in any given program area.

Resource Requirements: The CIRMS Science and Technology subcommittee chairs and co-chairs, working in cooperation with other experts in the field who have contributed to the development of a specific MPD, have estimated the personnel commitment, generally over the next three year timeframe, which will be required to carry out the Action Items and meet the program Objectives. Estimates are also given as to the costs of other related expenditures, such as for equipment, needed for a given program.

The MPDs listed in this report are divided into groups, reflecting the subcommittee structure of the CIRMS Science and Technology committee. The Medical Applications and the Industrial Applications and Materials Effects (IAME) retain the designations of MPD A.x.x and D.x.x respectively. For the new Radiation Protection (RP) subcommittee, formed by combining the Public and Environmental Radiation Protection (PERP) and the Occupational Radiation Protection (ORP), the designations used in the 2001 report, B.x.x and C.x.x, are retained in order to provide continuity. Input from the new subcommittee on Homeland Security has been included under Radiation Protection and designated E.x.x. The other new section dealing with cross-cutting Computational needs has been assigned the designation F. In each group, there is an Introduction followed by the text of the MPDs themselves. The first statement of an MPD is assigned a number that ends in zero, such as MDP D.8.0. Revisions are noted with ascending decimal suffixes. Thus, MPD A.3.3 indicates a third revision of a MPD in the Medical area. Because of confusion in the numbering of some PERP MPDs in the 1985 first "National Needs Report" and the second 1998 report, new numbers assigned to the MPDs in this area in the 2001 report. Appendix C presents a listing of CIRMS workshops that were held often prior to the formulation of a specific MPD and at which many of the MPDs were discussed.

A. MEDICAL MPDS

INTRODUCTION TO MEDICAL MPDS

Medicine was one of the first applications of ionizing radiation as Wilhelm Roentgen himself took an x-ray of a hand within a few days of his discovery in 1895. 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 (Radium-226, ^{226}R) 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 radionuclides, such as Iridium-192 (^{192}Ir), Palladium-103 (^{103}Pd) and Iodine-125 (^{125}I), have replaced radium for this use. Radionuclides are also used for diagnostic information, as Technetium-99 (^{99m}Tc), is commonly used for many nuclear medicine procedures.

Historically, the primary measurement laboratories such as the 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 Cesium-137 (^{137}Cs) and Cobalt-60 (^{60}Co). Recently a wide-angle free air ionization chamber and extrapolation chambers have been used for the measurement of brachytherapy sources, especially those having low energy emissions such as ^{125}I. A recent application of these types of sources is intravascular brachytherapy for preventing or inhibiting restenosis of cardiac vessels.

Today, the only traceable units of radiation quantities are Systeme International (SI) units. To enhance patient safety and minimize the risk of errors, the Medical Subcommittee will only accept SI units. Because the role of CIRMS is to deal with measurement and standards, only the use of SI units is acceptable. In particular, the following units should be used for the quantities listed. This is not intended to be a complete list. For the quantity activity, only Becquerels (Bq) shall be used (not Curies,

Ci). The Curie is an antiquated unit of activity based on radium. The new SI unit has as its basis the measurable quantity of disintegrations per second. For brachytherapy sources, the quantity expressing output is air kerma strength, having units of energy transferred per unit time at 1 meter distance (Gy-m^2/s; Gray-meter squared per second). The unit U = μGy-m^2/h is recognized as it is based on Systeme International (SI) units. Apparent activity is likewise not an acceptable quantity; it is based upon the output of a source and only vaguely related to the contained activity because it is dependent on the source geometry.

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 US resident. Breast cancer is the second leading cause of death by cancer in women. During their lifetimes, one in nine women will develop breast cancer. The Center for Disease Control (CDC) estimates that breast cancer mortality could be reduced by 30% 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 Measurement Program Descriptions (MPDs) in the first "CIRMS National Needs Report" (1985). This MPD, the first to be completed, proved highly successful (see Appendix B-2). 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 Food and Drug Administration (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. Another MPD was completed so that NIST now offers M80 and M120, as well as molybdenum beams as standard options. A new international standard is in development whereby there will be a new basis for these x-ray 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 total cost of these treatments is in excess of $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 detect clinically acceptable differences in the responses of patients who experience variations of as little as 5% in the delivered dose.

By far the most common types of radiation presently used to treat cancers are beams of x-ray and gamma-ray photons and electrons, although the use of brachytherapy sources is also common for treating some cancers such as prostate cancer. External electron and photon beams 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 sources of photons for brachytherapy treatments. A recent application of brachytherapy sources is in intravascular brachytherapy for the prevention of restenosis of coronary arteries. 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 distance just before they stop. Thus protons can be used to deliver more dose to the tumor and less to the surrounding tissue.

Historically, ionization chambers used to measure the output of machines used for radiation therapy were calibrated free in air in terms of exposure (or more recently air kerma) from a ^{60}Co unit. A standard protocol was then used to convert the measurement to absorbed dose to tissue. A more straightforward approach is 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, an MPD was included in the 1988 "CIRMS National Needs Report" for developing an absorbed dose to water standard based on a water calorimeter. A water calorimeter was developed, which has allowed NIST to provide an absorbed dose to water calibration factor for ion chambers immersed in water phantoms.

An application of brachytherapy radiation is to prevent restenosis following balloon angioplasty. Approximately 40% to 50% of patients having angioplasty experience

another obstruction of the arteries within six months. Studies have shown that radiation can slow or eliminate the regrowth of the lining of the injured vessel, delaying or preventing further obstruction. Intravascular brachytherapy involves introducing minute radioactive sources into the artery through a catheter, to deliver radiation directly to the inner surface of the vessel. These sources are in close proximity to the vessels so the determination of the dose at sub-millimeter distances from the source is important.

The need for high-spatial resolution dosimetry in radiation therapy is important not only for brachytherapy, but also for verifying the predicted dose distribution calculated using radiation therapy planning software. Modern treatments given using intensity-modulated radiation therapy (IMRT) particularly demand the ultimate in high-precision dosimetry.

With the development of improved methods of implanting brachytherapy sources in a precise manner for treating prostate cancer, there has been a tremendous growth in the use of ^{125}I and ^{103}Pd seeds for this modality. Air kerma strength standards for these brachytherapy sources are developed as new source designs become available, and are subjected to the customary procedures of standardization and comparison. The need for a ^{103}Pd standard as expressed in the 2001 CIRMS **Third Report on National Needs in Ionizing Radiation Measurements and Standards** has since been met.

Therapeutic application of radiopharmaceuticals with curative intent has been practiced since the early 1950s, mainly with Iodine-131 (^{131}I) and Phosphorous-32 (^{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 Yttrium-90 (^{90}Y) and Rhenium-186 (^{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, Strontium-89 (^{89}Sr), Tin-117 (^{117m}Sn), Samarium-153 (^{153}Sm), and ^{186}Re.

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 continue to be necessary.

Diagnostic applications for *in-vivo* imaging have grown to 8.2 million procedures annually in the United States alone. The chief reason for the 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 ^{99m}Tc, which has a six-hour half-life. The remaining 20% is accounted for by a score of other gamma-ray emitting radionuclides with half-lives from a few minutes to a few days. Some of the most common procedures include 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 is the short-lived positron emitters used for positron emission tomography (PET imaging). These include Carbon-11 (^{11}C) with a 20 minute half-life and Fluorine-18 (^{18}F) with a 2 hour half-life, which are ideal because of the ease with which they can be incorporated into biomolecules. The use of PET is growing at a tremendous rate.

MEASUREMENT PROGRAM DESCRIPTIONS

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

- A.2.3 Radioactivity Standards and Techniques for Nuclear Medicine
- A.3.3 Dose Mapping Systems for 3D Conformal Radiation Therapy and Intensity Modulated Radiation Therapy
- A.7.2 Absorbed Dose Standards for Brachytherapy Sources
- A.8.0 Liquid Based and Micro-Brachytherapy Sources

MPD A.2.3: RADIOACTIVITY STANDARDS AND TECHNIQUES FOR NUCLEAR MEDICINE

Objective: Develop NIST traceable standards and appropriate measurement techniques for radioactive isotopes used in nuclear medicine.

Background: Prior to approval of New Drug Applications (NDA) for radiopharmaceuticals by the US Food and Drug Administration (FDA), the manufacturers of those drugs must demonstrate the ability to make accurate measurements of the amount of radioactivity contained in the drugs. In addition to ensuring that measurements are being performed with the requisite accuracy at the manufacturing level, there is an increasing demand for standards that are relevant to measurements made in the clinic and radiopharmacy. This requires the development of "transfer standards" that relate measurements that are routinely carried out in the clinical setting to National Standards traceable to the National Institute of Standards and Technology (NIST). Often this takes the form of calibration factors for re-entrant ionization chambers, or "dose calibrators", for the solutions and containers that are used in the administration of these products. NIST has done this for a number of years. It is almost a standard procedure.

Of course, the most important impact of this program is increased safety to patients undergoing various radiological procedures. The Society of Nuclear Medicine estimates that about 12 million diagnostic (Positron Emission Tomography – PET and Single Photon Emission Computed Tomography – SPECT) and radiotherapeutic procedures are performed every year in the US 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.

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. In addition, the recent emphasis on transfer standards based on clinically useful geometries presents additional challenges as to choice of transfer instrument and requires a deeper understanding of the variables that influence the measurements.

NIST has developed a large number of standards for different radionuclides for nuclear medicine.

Therapeutic Radionuclides: Radiopharmaceutical manufacturers report that a number of ß-emitting nuclides, such as Lutecium-177 (^{177}Lu) and Holmium-166 (^{166}Ho), and Yttrium-90 (^{90}Y) are currently being developed for use in radioimmunotherapy. In addition, new uses for established radionuclides such as ^{125}I solution in balloons for use as a brachytherapy source for brain cancer continue to be pursued. Standards have already been established for most of these radionuclides, but there is an increasing demand for transfer standards. The low-energy radiations emitted by these radionuclides cause measurements made on these radionuclides to be sensitive to the solution density, container composition, and container wall thickness. Since these sources are therapeutic in nature rather than diagnostic, control of the dose and thus a precise standard is of great importance.

Diagnostic Radionuclides: Several new radionuclides are being developed as possible imaging agents in either Single Photon Emission Computed Tomography (SPECT) or Positron Emission Tomography (PET). Among these are Bromine-76 (^{76}Br), ^{88}Y, ^{94m}Tc, and ^{120}I. Standards for these radionuclides will enable researchers to properly calibrate their imaging systems, providing more reliable quantitative data. Just as important as the methodology to measure these radionuclides is the ability to accurately assay any radionuclidic impurities that may be present. For instance, the reaction used to produce ^{94m}Tc from a natural molybdenum (Mo) target also produces other technetium isotopes, some of which only decay by electron capture or isomeric transition, thereby making their identification difficult. Therefore, new methods will need to be developed to properly assay these impurities.

Basic Metrology Research: Necessary to the development and maintenance of primary and transfer standards is the study of experimental effects that have a bearing on measurement results for the various techniques currently in use or under development. These include liquid scintillation (LS) cocktail effects, investigation of alternative methods to efficiency tracing in LS counting such as the Triple-to-Double Coincidence Ratio method, optical effects in counting alpha emitters using liquid scintillation, theoretical modeling and experimental determination of correction factors in calorimetry, and geometry/composition effects in making measurements with ionization chambers.

Action Items:

1 – Continue to investigate and report on density/container effects in measuring ^{166}Ho and ^{177}Lu in commercial dose calibrators.

2 – Standardize the alpha-emitting radionuclide Astatine-211 (^{211}At).

3 – Develop standards for ^{94m}Tc and ^{88}Y and develop methodology for assaying radionuclidic impurities that may be present.

4 – Sustain basic research in metrology for radionuclides of interest to the medical community.

5 – Conduct workshops and seminars to bring together diverse organizations needed to accomplish the desired goals, including participation from universities, government agencies, for example the US FDA, NIST, and interested private companies.

Resource Requirements:

1 – A minimum of 2 person-years over the next three year time period is required to make substantive progress in this area. Resource commitments are needed from government agencies and laboratories, from universities and from private companies.

MPD A.3.3: DOSE MAPPING SYSTEMS FOR 3D CONFORMAL RADIATION THERAPY AND INTENSITY MODULATED RADIATION THERAPY

Objective: Establish standards for 3D dosimetry, quality assurance and treatment verification for conformal radiation therapy.

Background: Recent rapid advances of three dimensional (3D) Conformal Radiation Therapy (3D CRT) and Intensity Modulated Radiation Therapy (IMRT) have created an urgent need for the introduction of high-resolution three-dimensional methods of dosimetry, quality assurance and treatment verification. Conformal treatment techniques can deliver escalated doses to the lesion while minimizing the dose to the surrounding tissues, thereby potentially increasing the so-called therapeutic ratio, which is a measure of the likelihood that the disease will be controlled while minimizing radiation-induced complications. However, because of the very high dose gradients used in 3D CRT, an error in spatial dose distribution on the order of a few millimeters can lead to serious complications or even to fatalities. Therefore, in order to utilize the full clinical potential of these new technologies and therefore to assure the highest quality of radiation therapy care, measurement systems are needed for mapping, with at least millimeter isotropic resolution, cumulative 3D dose distributions in phantoms. Each such measurement must then be compared with the 3D treatment plan or the theoretical dose distribution. In addition, in the case of Intravascular Brachytherapy dosimetry, spatial resolution on the order of 0.1 millimeter is required, as the dose from some sources that are used in clinics can fall by as much as 10 % over 0.1 millimeter distance.

Planar dosimeters such as radiographic film have been traditionally used in conjunction with various phantoms for measuring dose distributions. The introduction of the tissue-equivalent, self-developing radiochromic film, capable of recording doses in the therapeutic range has enhanced applications of film dosimetry and has enabled its use for quality assurance (QA) of conformal therapy. In addition, continuous development of new materials that may substitute the film, for example plastic scintillators or phosphor plates, makes it possible to obtain on-line reading of dose distributions in selected planes.

None of the above methods however can measure dose distributions in three dimensions with high enough spatial resolution that is needed wherever high dose gradients are employed in the treatment plan. High dose gradients are characterized by

lack of electronic equilibrium that is normally required for applying standard dosimetry tools such as ion chambers or diodes. Therefore there rapidly emerges a need for three-dimensional chemical dosimetry methods, based on measuring chemical changes that are induced by radiation in tissue-equivalent solids or gels.

Gel Dosimetry: Various tissue-equivalent gel dosimeters have been repeatedly proposed since the fifties. By their very nature, gel dosimeters are chemical dosimeters in which the radiation-induced chemical change is limited to the site of origin and is prevented from spreading all over the gel volume by the presence of the gelling matrix. The chemical effect might be for example a pH change, a color change, or optical density change.

In the past, a gel dosimeter would be sliced and a sample taken for subsequent chemical analysis. Such procedures were very time consuming and therefore impractical. However, the commercial introduction of tomographic imaging techniques such as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) has made it possible for the first time to measure 3D dose distributions from irradiated gels in a noninvasive fashion. And the standardization of diagnostic image formats (DICOM) provides the basis for developing standard methods for correlating 3D treatment plans and 3D phantom data.

There are two major classes of gel dosimeters: radiochromic gels and polymer gels. In both classes the primary step of the dose response is the radiolysis of the solvent, which is the main component of the gel and is most often water. In a radiochromic gel the various products of solvent radiolysis (either red-ox or free radical) induce a color change of a dye that is dispersed in the gel. The spatial distribution of the color in the gel is then representative of the dose distribution.

In polymer gels the free radical products of the solvent radiolysis initiate chain polymerization of vinyl or acrylic monomers which are dispersed in the gel, and the resultant polymer particles become permanently attached to the gel matrix, thereby forming a 3D image of the radiation dose distribution.

Each class of gel has its own advantages and disadvantages. For example, the radiochromic gels can be exposed to air, whereas the polymer gels must be sealed in special phantoms that protect them from atmospheric oxygen, which inhibits their dose response. On the other hand, the polymer gels produce permanent 3D images, whereas radiochromic gels suffer from diffusion of the dye molecules through the gel, which leads to the blurring of the dose distribution pattern with time. Several types of gel

dosimeters are beginning to be available commercially, and more are under development.

MRI and Optical Computerized Tomography (OCT) for Gel Dosimetry: Two types of tomographic imaging have been proposed as readout methods for gel dosimetry: MRI and optical tomography. Gels can be made to change their water proton relaxation rates upon irradiation, and MRI scanning protocols exist that can be used to map out the spatial distribution of relaxation rates in the gel from the MRI data. A calibration of relaxation rates to the dose allows for creating 3D dose maps from the MRI scans of such gels.

Alternatively gels can change their color or optical density in proportion to the absorbed dose. Optical Computerized Tomography (OCT) can be used for scanning such gels, to produce maps of optical attenuation coefficients that are then converted to dose distributions. Various types and designs of OCT scanners are currently under development at several research institutions. Among potential advantages of OCT scanners over MRI are the cost factor, accessibility, spatial resolution, and image noise reduction. An example of an irradiated gel dosimeter is the BANG® polymer gel dosimeter manufactured by MGS Research, Incorporated shown in Figure A.3.3a. The gel has been irradiated with an IMRT delivery that produced a dose distribution designed to conform to a complex three-dimensional shape. The absorbed dose is proportional to changes in the optical density of the gel as observed by localized cloudiness in the polymer gel. Data was developed using this type gel using a CT laser scanner. Figure A.3.3b shows the comparisons between the calculated dose distributions (shown in green), EDR-2 film dosimetry (shown in red) and BANG gel measurements (shown in blue). The comparisons are shown for two planes through the gel, within which the dose distributions are quite different. Agreement between calculations and measurements is shown to be excellent.

Other 3D Dosimeters: At least two new classes of 3D dosimeters are currently under development: radiochromic solid materials that can change color when irradiated, and gel scintillators that emit light when irradiated. Radiochromic solids are by nature cumulative 3D dosimeters and may be scanned by light transmission OCT just like the gels are. The 3D scintillators may be used for on-line applications and will require a special light emission OCT apparatus. They may find use in 3D characterization of dose distributions from brachytherapy sources or irregularly shaped stationary external beams.

Needs: A single most important objective for new measurement protocols that are needed should be the development of a reliable system of data correlation between the 3D treatment plan and the 3D phantom measurement. The new system should be readily accessible to medical physicists in hospitals, as these measurements would be used on a routine basis to confirm the quality and safety of conformal radiation therapy equipment, typical treatment protocols and possibly even individual treatment plans. These new measurement protocols would have to be standardized and traceable to measurements performed periodically at NIST or at Accredited Dosimetry Calibration Laboratories (ADCLs).

Phantom Design: Phantoms should be designed for spatially correlating the treatment plan data with 3D dosimetry. Fiducial markers must be well detectable, with sufficient spatial resolution, by all imaging modalities that are to be employed in the initial scanning of the phantom and in obtaining the 3D dosimetry data. It has been generally assumed that 1 mm uncertainty is acceptable, although calls for sub-millimeter resolution are increasingly common. Therefore, the design of fiducial markers that are necessary for image fusion, for example of x-ray CT and OCT data sets, or MRI and CT, is a non-trivial task. In addition to fiducial markers, the phantom design should also include the shape of the outer contour that may be utilized in contour-based image fusion algorithms. Also, various inserts providing treatment targets as well as gels or other 3D dosimeters should be carefully designed for various specific applications, such as equipment/protocol QA, dosimetry or patient treatment verification for various types of treatment. It can be anticipated that different sets of phantoms will have to be designed for different tasks.

Software: Computer software must be developed for user-friendly handling of 3D data generated by the radiation treatment plan (RTP) and by the 3D dosimeter. Both interactive and automatic features must be provided for manipulating the 3D data matrix with image fusion, dose and spatial calibration, 3D dose maps with volume rendering and spatial registration, isodose and profile plotting, dose difference and isodose distance maps, and quantitative treatment evaluation functions such as dose and dose difference volume histograms, Conformality Index (CI), gamma function etc. The software must be capable of both importing and exporting DICOM and DICOM-RT files.

Calibration: New 3D dosimeters, including gels and solids, are currently under development that in addition to measuring relative dose distributions will have a reproducible dose response that is needed for measuring the absorbed dose with uncertainty not greater than 2%. The focus of this effort is on physical/chemical factors

that affect the reproducibility of the dose response, in parallel with modeling the dose response theoretically. New methods of calibrating these new 3D dosimeters will have to be developed and then standardized.

Measurement Protocols: First, sets of specially designed phantoms will be irradiated with static beams of increasing degree of complexity. Then 3D dynamic irradiations will be performed using sets of phantoms and according to protocols yet to be designed. Protocols that are currently in use with film dosimetry will be of limited utility while using 3D dosimeters that are scanned tomographically, and therefore new protocols will have to be carefully designed for each task.

Patient Treatment Verification: An exemplary protocol for patient treatment verification could include the following steps:

- CAT-scan the patient (Computerized Axial Tomography-scan).
- Write the radiation treatment plan (RTP) for the patient.
- CAT-scan the phantom.
- Calculate the dose distribution in the phantom if "treated" using the patient's RTP.
- Apply the patient's RTP to the phantom, i.e. "treat" the phantom.
- Measure the dose distribution in the phantom by MRI or OCT scanning.
- Import the RTP and the phantom 3D data sets to a computer.
- Fuse the RTP and the phantom data sets.
- Compare the two data sets by using quantitative evaluation functions, such as dose difference maps and dose difference volume histograms, 3D isodose distance maps, Conformality Index (CI), gamma function and the like.
- Export the final report in a standardized format that enables interactive evaluation by medical physicists.

Despite having been noted in previous CIRMS "National Needs Reports," activities in the areas addressed by this MPD have been limited to a few research and development projects fund by the National Institutes of Health (NIH), mostly through its Small Business Innovative Research (SBIR) awards.

Action Items:

1 – Establish a system for gathering data and correlating data between 3D treatment plans and 3D phantom measurements.

2 – Improve 3D phantoms through the use of fiducial markers so that dosimetry can better correlate with treatment plans.

3 – Develop user-friendly computer software for handling data generated by radiation treatment plan (RTP) and 3D dosimetry.

4 – Establish 3D dosimeter calibration protocols such that the absorbed dose response varies <2% in inter-laboratory comparisons.

5 – Develop quality assurance, acceptance testing and commissioning measurement protocols that lead to patient treatment verification.

6 – Conduct workshops and seminars to bring together diverse organizations needed to accomplish the desired goals, including participation from universities, government agencies, e.g. NIH, FDA, NIST, and ADCLs and interested private companies.

Resource Requirements:

1 – A firm commitment to a minimum of 5 person-years, preferably at least 10, over the next four year time period is required to make substantive progress in this area. Resource commitments are needed from government agencies and laboratories, from universities and from private companies working in collaboration with each other.

Figure A.3.3a – Irradiated BANG gel dosimeter
(courtesy of MGS Research, Incorporated)

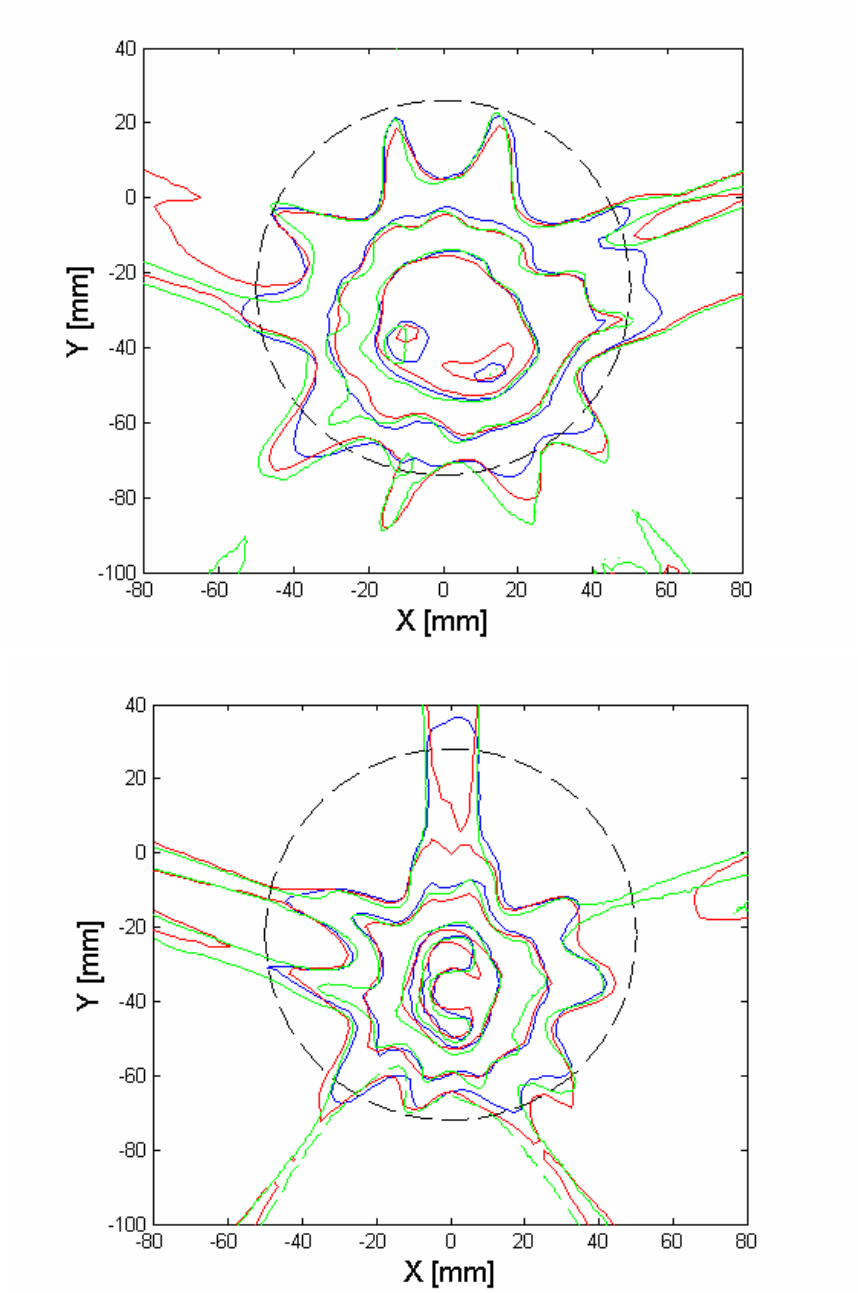

Figure A.3.3b – Two different planar comparisons of dose maps
Green = calculated dose distributions
Red = EDR2 film dosimetry
Blue = BANG gel dosimetry
(courtesy of Cheng-Shie Wuu, Columbia University, and MGS Research)

MPD A.7.2: ABSORBED DOSE STANDARDS FOR BRACHYTHERAPY SOURCES

Objective: Develop NIST traceable absorbed dose standards for brachytherapy sources.

Background: Brachytherapy sources are coming into wider use for such applications as prostate implants and intravascular treatments for inhibition of restenosis. Presently, NIST offers air-kerma calibrations for these sources. Conversion of the air-kerma strength to a three dimensional dose-distribution in a medium is a long process, involving Monte Carlo analysis and in-air measurements of anisotropy and spectra. Radiochromic film is a convenient tool for some of this work, but requires construction of precise phantoms for each source geometry. Direct measurement of the dose-rate by an ionization chamber in a medium is a more direct method and would serve to tie together the theoretical modeling and the in-air measurements. It will also enable a direct measurement of source anisotropy.

With the increasing acceptance of implants as a leading method of treating cancer as well as a number of common non-cancerous conditions, the brachytherapy source manufacturers are responding by creating new source designs to compete for a part of the large market. Direct measurement of new source designs offers the advantage of increased accuracy and shorter validation times for clinical applications.

An alternative device for brachytherapy applications is a miniature x-ray generator. This device allows radiation to be delivered to small volumes of tissue through a needle-like applicator that can be inserted into the target tissue. Procedures for calibration of this device must be developed and implemented before it can be used in the clinic.

Action Items:

1 – Using three different detector systems, continue to characterize their reliability in measure dose from different brachytherapy sources.

2 – Adapt detector housings and software to enhance absorbed dose measurements for brachytherapy sources.

3 – Sustain sufficient NIST and industry support to complete the objectives of this MPD.

Resource Requirements:

1 – A minimum of 2 person-years per year over the next three year time period is required to sustain efforts in this area with personnel being provided by both NIST and its industry partner.

Figure A.7.2 – Well-ionization chamber for clinic use (courtesy of NIST Ionizing Radiation Division)

MPD A.8.0: LIQUID-BASED AND MICRO-BRACHYTHERAPY SOURCES

Objective: Develop a NIST traceable standard for liquid-based brachytherapy sources, and micro-brachytherapy sources, and transfer this standard to the ADCLs.

Background: Liquid based and micro-brachytherapy sources are coming into wider use for therapy applications. Recently, NIST developed a "nuclear medicine" standard based upon a contained activity measurement. However, such an activity measurement is not sufficiently precise for use in radiation therapy. A preferred standard would consist of a statement of the emitted radiation from the source.

A critical need in this area is a technique to transfer the calibration from the assay of a sample of an unsealed radioactive source, to the calibration of the unsealed source in the environment used for treatment. In some cases, the unsealed source is introduced by a catheter into a balloon, which is implanted into the target tissue. The effect of the balloon, as well as the specific geometry of the unsealed source, must be addressed.

Action Items:

1 – Adopt the "brachytherapy" model for calibration, assay and dosimetry of liquid-based and micro-brachytherapy sources rather than the "nuclear medicine" model.

2 – Establish a system for calibration of dose calibrators by the ADCLs for liquid-base and micro-brachytherapy sources.

3 – Advance the quantitative, image-based dosimetry for liquid-based brachytherapy and micro-brachytherapy and conduct a consensus building workshop to cover this topic.

4 – Study the conversion from "contained activity" to "emitted radiation" standards for liquid-based and micro-brachytherapy.

Resource Requirements:

1 – A minimum of 2 person-years per year over the next three year time period is required to launch into these objectives. Some partnerships between NIST and industry are warranted in this area.

B/C/E. RADIATION PROTECTION MPDS

INTRODUCTION TO RADIATION PROTECTION AND HOMELAND SECURITY MPDS

When CIRMS formed the subcommittees of the Science and Technology Committee, a distinction was made between the radiation measurements as related to radiation protection of the members of the public at-large and the environment and to radiation protection in the workplace. Two subcommittees were formed to address these needs: the Public and Environmental Radiation Protection (PERP) subcommittee and the Occupational Radiation Protection (ORP) subcommittee. Notes A and B at the end of this section provide background information on these two areas. Despite some differences in techniques and in regulations for these two areas, there are a number of overlapping issues in radiation measurement in the two areas and these two groups have worked jointly in several areas. In addition, the emerging concerns over radiation protection of first-responders by the Department of Homeland Security (DHS) also fit into this area in that such concerns also involve worker as well as public radiation protection. While CIRMS has formed an independent subcommittee to deal with Homeland Security interests, this nascent subcommittee's interests are included herein.

Since the public protection from environmental radiation and workplace radiation protection problems share many common characteristics, the two subcommittees a single merged subcommittee was formed, the Radiation Protection (RP) subcommittee. This broader title encompasses both of the previous areas and is more representative of the description of departments or divisions in government, industry or academia that are charged with monitoring and controlling radiation as it would affect persons in a situation where they are or can be exposed to irradiation sources.

The Radiation Protection subcommittee deals with radiation measurement issues for workers in the nuclear industry and in various other end-use areas that deal with radioactive isotopes, such as nuclear medicine, biomedical research and agriculture. Of concern are the protection of the workers and the members of the public at-large. This includes, for example, those engaged in nuclear power generation, nuclear research performed by national laboratories, universities, contractor laboratories in the private sector, environmental protection, nuclear weapons research and development, waste

handling, storage, transportation, disposal, decontamination and decommissioning of contaminated sites and structures, and Homeland Security related activities. There are over one million workers employed within the nuclear industry, at Department of Energy facilities and facilities licensed by the Nuclear Regulatory Commission (NRC) and the states. This is a several billion dollar industry and its viability depends on the protection of both these workers and the members of the public and of the environment.

The workplace environment must be fully characterized in order to protect the health of radiation workers. Since radiation cannot be detected by the human senses, workers depend upon measurement tools and techniques to monitor their exposure to radiation. Planning, controlling and monitoring the exposures to ionizing radiation requires accurate, reliable instrumentation to establish dose-rates, indicate high exposure areas, and to control the spread of contamination in both the workplace and in the public environment. The day to day prevention and minimization of radiation exposure to workers and members of the public requires the use of sophisticated portable and/or installed instruments whose results are verified by bioassay and dosimetry programs that also rely upon sophisticated instrumentation. The dosimetry and bioassay results constitute the legal record of the worker's exposures. However, measurements made with reliable instrumentation prior to entry and during work in an area of potential radiation exposure are essential to minimizing worker exposures and in complying with applicable federal and state radiation protection regulations and the principal of keeping radiation exposures *As Low As Reasonably Achievable* (ALARA). ALARA is used throughout industry as a guiding principle for the control and monitoring of a worker's radiation exposure.

In recent years, an increasing number of sophisticated instruments and dosimeters have been derived from the increased sophistication and miniaturization of electronics. However, performance evaluations and inter-comparisons have shown the response characteristics of such instruments remain dependent on such factors as the environmental conditions, the dosimeter processor, and the quality of the calibrations, and the skill and experience of the person analyzing results. The reliability of the entire measurement system has not improved with the increasing sophistication of the measurement tools. For example, in the case of personnel dosimeters, recognition of the deficiencies led to the establishment of accreditation programs for dosimetry processors. This program has significantly improved the overall performance of dosimetry processors' measurements in the US. However, maintaining these improvements requires continued diligence.

Although new technology provides more and more information, better sensitivity and analytical speed, the work environment and its regulations require more accurate measurements at lower dose-rates. A large fraction of the workers continue to be exposed to radiation in the medical, nuclear power, and research industries, but must meet regulatory demands for lower worker exposures and improved control of the radiation environment. Today many workers are involved in environmental cleanup activities and these workers encounter a different radiation environment than one would expect in a typical work environment.

Expansion of accreditation programs that also include new measurement techniques, improvement of calibration techniques and capabilities, improvement of the control, or understanding of limitations of different the measurement techniques, and development of better new measurement techniques results in improved measurement accuracy and reliability. In turn, improved measurement accuracy and reliability assists in protecting the radiation worker within the workplace, and members of the public and the environment. The improved accuracy and reliability of the measurements and the monitoring and control of the radiation environment increase public confidence in the nuclear industry. This will improve public confidence in the industry and will lead to its continued viability and acceptance.

Measurement tools for accurate assessments are fundamental to for 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 in nuclear emergency response and routine cleanup require rapid reduced-cost turnkey analytical methods and technologies with higher selectivity and sensitivity that yield technically and legally defensible analyses. The development of these measurement tools, and their calibrations, will be based on pooling multi-disciplined expert teams. This requires considerable resources that can be found only through national initiatives. CIRMS goal is to provide a forum to identify areas of opportunity for reliable new measurements and standards development, to produce a strategic plan, and to initiate cooperative and leveraged funding support to meet current and future needs in occupational, environmental and radiation protection bioassay radionuclide metrology needs. In this regard, many of the interests in the area of Homeland Security, especially as related to the needs of first-responder, fall within this context.

MEASUREMENT PROGRAM DESCRIPTIONS

The following MPDs address measurement and standards needs in radiation protection and Homeland Security areas:

Public and Environmental Radiation Protection

B.7.1 Traceability to NIST for Reference, Monitoring and Service Laboratories

B.8.1 Sorption of Radioactive Elements in Contaminated Soils and Sediments and Urban Structural and Other Materials

B.9.1 Atom-Counting Measurement Techniques for Environmental and Radiobioassay Monitoring

Occupational Radiation Protection

C.3.3 Intercomparison Transfer Standards for Neutron Source Calibrations

C.4.3 Improvements for *In-vivo* and *In-vitro* Radiobioassay Metrology

C.17.2 Improved Radiation Measurement Infrastructure for Occupational Radiation Protection

C.19.1 NIST Traceability for Low Dose -Rate Calibrations

C.20.1 Implementation of Support for Personnel Dosimetry Proficiency Testing per ANSI N13.11

Homeland Security

E.1.0 Emergency Radiological Response

E.2.0 Performance Criteria for Service Laboratories Performing Personnel Radiation Exposure Dose Assessment Using Solid Matrix Biological Materials

E.3.0 Performance Criteria for Specialized Teams Supporting Medical Response during Nuclear and Radiological Emergencies including Terrorism Incidents

Within the Homeland Security area, several organizations are, as of November 2004, working on documents and programs that will assist in dealing with the needs in this area. Below is a table that attempts to summarize the current status of some programs underway as well as to point to major gaps and areas that require future attention. These three MPDs are but a partial focus, and, as the CIRMS Homeland Security subcommittee evolves, it will up-date a consensus matrix that can be posted on the CIRMS web-site for comment.

Measurement Domain	**Initiatives Undertaken**	**Target Document and/or Audience**	**Related Concerns**
Cytogenetic Biodosimetry	IAEA document in DRAFT format	ISO/DIS 19238 balloted in 2003	ISO standard for triage in progress
Biophysical Dosimetry	Intercomparison study of dosimetry methods needed	**Need initiative for an internal standard method**	Correlative *in vivo* research
Radiation Bioassay Whole-Body Counting	REALnet Workshop CIRMS Meeting October 27, 2004	Reference and satellite laboratories	**Need initiative for deployment**
Hematology		Reference laboratories	**Need initiative for deployment**
Clinical Symptoms and Biodosimetry	Training programs	Physicians and Radiological Assessors	**Need to address first responders**
Software Tools	Biodosimetry Assessment Tool (BAT)*	Physicians and Radiological Assessors	**Need to address first responders**

*See: <www.afrri.usuhs.mil/www/outreach/biodostools.htm#software> for details.

MPD B.7.1: TRACEABILITY TO NIST FOR REFERENCE, MONITORING AND SERVICE LABORATORIES

Objectives: Develop a national approach, consistent with ANSI N42.23, for reference, monitoring, and service laboratories to establish and maintain traceability to NIST

Establish NIST traceability for the reference laboratories of sponsored performance evaluation programs

Background: The term "traceability" has become a complex concept having subtle differences in meaning depending on the specific application and the organization effected. In 1996, as a result of the American National Standards Institute (ANSI) process, a national standard was developed for the purpose of clarifying a process of how laboratory measurements can become traceable to NIST. The 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.

ANSI N42.23-1996 was developed to address a national concern to establish a national approach to measurement assurance 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) process to support the optimization of 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/administering organization and the reference, monitoring and service laboratories.

There are currently a few measurement programs related to radioassay laboratories. These include the US Environmental Protection Agency's PE PROVIDER Program

administered by the National Voluntary Laboratory Accreditation Program at NIST; the NIST Radiochemical Intercomparison Program (NRIP) that provides NIST traceability to service laboratories that analyze environmental and radiobioassay performance testing samples; the US Department of Energy Laboratory Accreditation Program (DOELAP) for DOE's in vitro and in vivo bioassay programs is for which the DOE's Radiological and Environmental Sciences Laboratory (RESL) is the reference laboratory; the DOE Mixed Analyte Performance Evaluation Program (MAPEP) at RESL that provides radiological and mixed analyte (radiological plus organic and inorganic) samples to commercial and contractor analytical laboratories supporting DOE cleanup activities across the DOE complex; and the Radiological Measurement Assurance Program (RMAP) that RESL conducts for the NRC to provide MQA for the NRC's Monitoring Laboratory. There have also 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.

Recently, the Department of Homeland Security (DHS) initiated an evaluation of the need for standards and performance testing programs for emergency response radiological laboratories. Through NRIP a radiological emergency preparedness evaluation of laboratory capabilities were tested with an eight-hour turnaround. Preliminary results indicated uneven capabilities, and spotlighted a need for emergency preparedness assessments within the laboratory community that DHS would call up in a radiological event. Additionally, there is a renewed need to develop rapid methods for radiological emergency response. Another need that has been identified by the radioassay community is the development of a MAP for the newly developed 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 (the Multi-Agency Radiation Survey and Site Investigation – MARSSIM and the Multi-Agency Radiochemistry Laboratory Analytical Procedures – 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 consistent national approach to Measurement Assurance 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.

This MPD was recognized as a major priority in November of 1996. Since the initial formulation of this MPD, 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. The ANSI standard defined a statistically-based NIST traceability criterion that incorporated the measurement uncertainties of both NIST and the source manufacturer. This standard is currently in the five-year revision process. The ANSI standard N42.23 entitled "Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories" was published the second quarter of 1997. NIST subsequently 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. NIST has recently issued for comment a policy statement that defines NIST traceability. The interpretation of the NIST traceability policy may impact the guidance provided in ANSI N42.22 and N42.23.

Action Items:

1 – NIST should establish a steering committee comprised of NIST and government and commercial laboratory stakeholders. It should work closely with the working group that is being established to revise the current version of ANSI N42.23. This steering committee should focus on:

a) Recommending the program elements required at NIST to support a consistent national approach to Measurement Assurance, and facilitate the necessary working relationship between NIST, reference, monitoring and service laboratories and the administrating agency.

b) Developing a "needs" table of sample matrix, radionuclides, media type and analyte concentration level. Test matrices would have to be specific to the needs of each program. These MAPs will vary greatly, from drinking water standards, to

radiobioassay standards, to soil samples, to emergency responder tests. The levels needed would also be program specific.

c) Developing guidelines for the development of measurement quality objectives for the preparation and distribution of performance testing samples by NIST and the reference laboratories.

d) Developing guidelines and criteria for sample preparation procedure verification and validation applicable to test matrices and analyte concentrations prepared by NIST or the reference laboratories.

e) Establishing common testing requirements for NIST traceability between NIST and the reference /participating laboratories.

f) Developing quality assurance assessment criteria for conducting onsite assessments of the reference laboratories.

g) Developing a consistent mechanism for funding NIST support of a national approach to MQA involving government and private testing laboratories.

h) Make recommendations on resources at NIST that would be needed to adequately support this effort. These might include but are not limited to: additional scientific and staff, expanded measurement capabilities, dedicated laboratory facilities, and additional programmatic oversight and management.

Resource Requirements:

1 – For the Radiochemical Intercomparison Program (NRIP), three full-time employees or contractor equivalent at NIST are needed for program administration, development of the necessary technical capability and the preparation and analysis of the test samples of the programs. The scientists will also be responsible for the development and maintenance of the radioanalytical procedures, and the development of the test sample preparation and verification protocols.

2 – Sufficient and dedicated laboratory facilities and resources to conduct the radioanalytical portion of the programs.

3 – Maintenance of calibrated nuclear instrumentation and primary test solutions for the conduct of the programs.

4 – Sufficient resources for programmatic oversight and management to update the programs and meet the communities needs.

NOTE: In the CIRMS "Second Report on National Needs in Ionizing Radiation Measurements and Standards," published in October, 1998, this MPD appeared as MPD B.1. A new MPD number has been assigned, MPD B.7, to avoid confusion with MPD B.1 that had appeared in the first CIRMS "Report on National Needs in Ionizing Radiation Measurements and Standards," published in January, 1995, that covered a different topic.

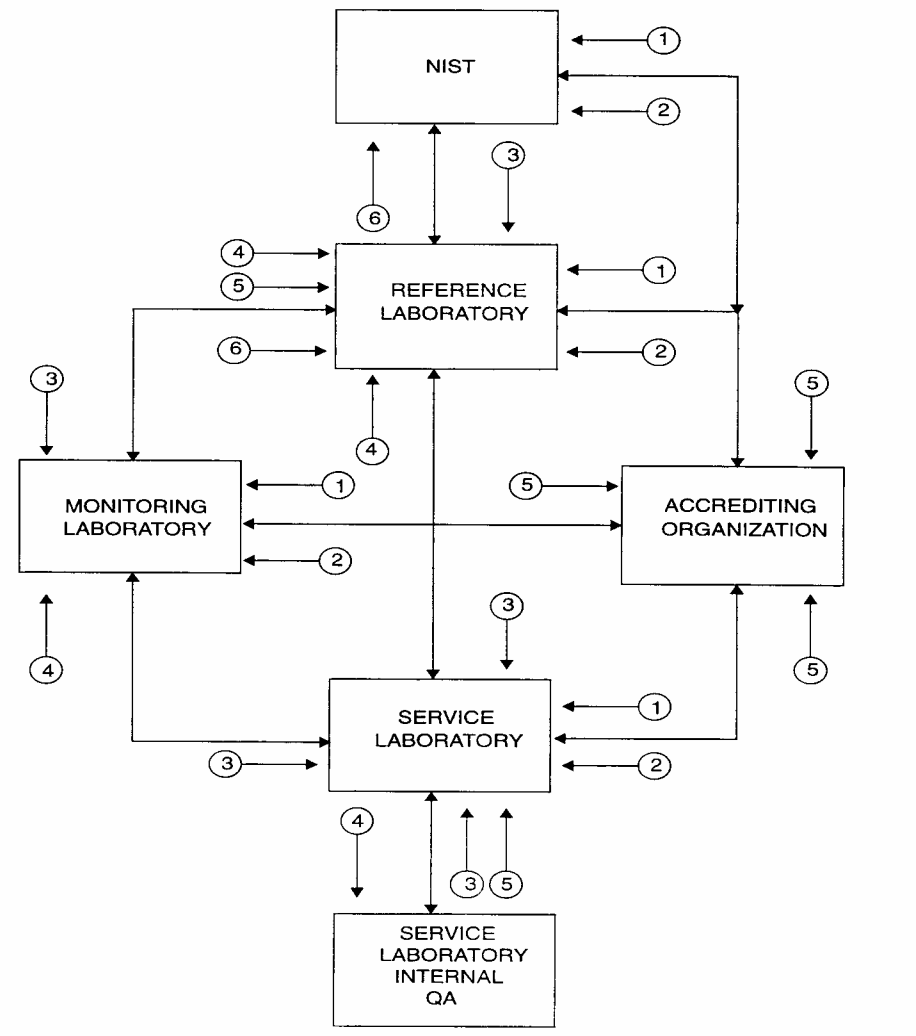

Figure B.7.1 – Diagram of national performance testing program per ANSI N42.23

MPD B.8.1: SORPTION OF RADIOACTIVE ELEMENTS IN CONTAMINATED SOILS AND SEDIMENTS AND URBAN STRUCTURAL AND OTHER MATERIALS

Objectives: Develop a rigorous, standard protocol for sequential extractions of radiologically-contaminated soils, sediments, and urban structural and other materials.

Apply the standard protocol to produce NIST Standard Reference Materials (SRMs) certified for radionuclide fractionation.

Background: Extensive areas of soils and sediments have been documented as having significant radioactive contamination. It is critical to evaluate the sorption of the radionuclides to soils and sediments to assess the potential of mobilization through the ecosystem, evaluate the health risk to man, and to develop cost-effective strategies for environmental remediation.

Within current budgetary constraints, there are far more radiologically-contaminated sites at former nuclear weapons and industrial facilities than can be effectively dealt with on a reasonable time scale. 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 transport and biological availability" of the relevant contaminating radionuclide species is a critical issue. There is a more pressing need to remediate sites where the radionuclides may be in more mobile physico-chemical forms than sites where the contaminants are known to be firmly fixed in the matrix. Recent studies have shown that the speciation of contaminating radio-elements plays a very important role in dictating whether a radionuclide may move into the environment and the food chain. How then does one measure environmental transport and bioavailability of contaminant radionuclides?

Unfortunately, there is no widely accepted method available for measurement of this parameter. On the other hand, numerous studies have been performed that 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 potential mobility of

that radioelement in the environment and its bioavailability. 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. A "refractory" label is often assigned should the analyzed material respond to one of the latter, 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 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 over how sequential extraction results should be interpreted and which specific procedures should be applied. There is an important gap in the confidence to use such methods, which otherwise have great appeal, to assess the environmental availability of radioactive elements in contaminated materials. The use of sequential extractions to characterize the nature of radiological contamination in a material is a departure from the normal analysis style that 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 inter-comparisons of different laboratory methods. This need overlaps, but does not duplicate, the needs expressed in CIRMS MPD B.3 "Radioactivity Standards for Waste Management and Site Remediation" of the "Second Report on National Needs in Ionizing Radiation Measurements and Standards," published in October 1998. 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 radionuclide partition 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 radionuclide partition 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 will be designed to assess the radionuclide partition of benchmark actinide elements (Uranium and Plutonium) in natural soils and sediments. In addition, several "indicator" stable elements (Iron, Aluminum, Cesium, Strontium, Zirconium, Carbon, etc.) will be included during the

development stage in order to appraise more assuredly the various phases attacked during each extraction step.

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

Action Items:

1 – Conduct a second round of the extraction protocol optimization on SRM 4354 (Gyttja, a high organic content fresh water Canadian lake sediment) to determine how robust the protocol is in inter-laboratory comparisons.

2 – Finalize the documentation of the extraction protocol.

3 – Conduct inter-comparisons using the extraction protocol to evaluate the reproducibility among laboratories.

4 – Initiate the certification of a new line of natural-matrix environmental SRMs for extraction of radionuclides.

5 – In support of the extraction protocol results, develop *ab initio* molecular orbital computations for radionuclides on mineral surfaces and interior planar positions to evaluate the energetics of the interactions.

6 - Develop surface contaminated urban materials (concrete, metal, glass, paper, marble, and other materials).

7 – Develop an expert consensus draft sequential extraction protocol to assess radionuclide mobility from urban materials.

8 – Optimize the sequential extraction protocol for assessing radionuclide mobility from urban materials.

9 – Develop suite of surface and volumetric radionuclide spiked Standard Reference Materials.

Resource Requirements:

1 – Two NIST full-time employees (FTE) are needed to conduct Action Items 1, 2, 3 and 5 above; ICP-MS support for stable element analysis, computational power for the *ab initio* computations. Estimated cost $100,000 per year over a 10 year period.

2 – Two full-time employees (FTE) at NIST to coordinate and conduct the certification of the new line of natural-matrix environmental and urban matrix SRMs for extraction of radionuclides. Estimated cost of $350,000 per year over a 20 year period.

The study envisioned would consist initially of a relatively small group of professionals (approximately 4-6 scientists in three 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 inter-laboratory 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.

Figure B.8.1 – Soil sampling for radioactive contamination

NOTE: In the CIRMS "Second Report on National Needs in Ionizing Radiation Measurements and Standards," published in October, 1998, this MPD appeared as MPD B.5 and the related MPD B.3. A new MPD number has been assigned, MPD B.8, to avoid confusion with MPD B.5 that had appeared in the first CIRMS "Report on National Needs in Ionizing Radiation Measurements and Standards," published in January, 1995, that covered a different topic, and MPD B.5 in the second report.

MPD B.9.1: ATOM-COUNTING MEASUREMENT TECHNIQUES FOR ENVIRONMENTAL AND RADIOBIOASSAY MONITORING

Objective: Develop the capability and resources to provide NIST traceable reference materials and analytical performance testing of long-lived radionuclides in various media by mass spectrometry.

Background: Certain radiochemical analyses, especially those of the long-lived alpha emitters, can be long, laborious and costly. It is expected that cleanup and site remediation programs related to Department of Defense programs will require millions of assays over a period of 30 or more years, costing many billions of dollars. Furthermore, rapid analysis of radionuclides for emergency response and isotopic ratio determination of source identification are required. Thus, a need exists for reducing the cost of these programs by developing techniques that: (1) use atom-counting to reduce measurement time spent by factors of 10 per assay while increasing sensitivity by a factor of 1000, and (2) extends analytical sensitivity and selectivity over conventional radioactivity measurement techniques, and (3) 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 a number of radionuclides. Recently, the Brookhaven National Laboratory has demonstrated that Plutonium-239 (^{239}Pu) in urine samples can be measured accurately down to the microBq per liter. 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 (LANL) and the Lawrence Livermore National Laboratory (LLNL). The application of atom-counting to bioassay will produce cost savings and will enable health physicist to document internal uptakes orders of magnitude better than current levels. In addition, the mass spectrometric technique yields additional isotopic information to that obtained from traditional radioactivity measurement techniques.

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. NIST has recently conducted a Cesium-137 (^{137}Cs) "proof-of-principle" experiment using Resonance Ionization Mass Spectrometry (RIMS – Figure B.9.1). This demonstrated for the first time that a Glow Discharge source with

external laser interrogation and selection is possible. An atom-counting technique aims to incorporate environmental materials into a RIMS system, which has sensitivities in the part-per-trillion range or better, is under development. This requires development of a source that can generate neutral atoms with appropriate constant wave beam intensity, width, and other characteristics. Furthermore, new mass spectrometric technique capabilities reported at the 2002 and 2003 Radiobioassay and Radiochemical Measurements Conference are being extended to be competitive with conventional radioactivity measurement techniques for radionuclides with half lives as short as a few tens of years (for example ^{90}Sr and ^{137}Cs).

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

A joint meeting of the ASTM D19.04 Subcommittee on Radioactivity in Water and the ASTM 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 plutonium (Pu), Technetium-99 (^{99}Tc) and Iodine-129 (^{129}I) were discussed. ASTM standard C1310-95 for the application of Inductively Coupled Plasma - Mass Spectrometry (ICP-MS) for ^{99}Tc, Thorium-230 (^{230}Th) and Uranium-234 (^{234}U) in soils after dissolution was successfully balloted and has become available to the technical community. A standard developed for the analysis of ^{235}U and ^{238}U in urine to support radiobioassay programs is currently in the ASTM balloting process.

Other recently published ICP-MS methods include those for

- Radium-226 (^{226}Ra) in soils and water related to uranium mining and milling remediation efforts in Texas.
- Neptunium-237 (^{237}Np), ^{232}Th, ^{235}U and ^{238}U for urine bioassay developed at the Lawrence Livermore National Laboratory.
- ^{237}Np in oily waste developed at the Oak Ridge National Laboratory.
- 99Tc 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 ^{239}Pu 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 (LANL), 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. Prior to 2000, the Brookhaven National Laboratory successfully applied Fission Track Analysis to the assay of ^{239}Pu in urine specimens collected from the Marshall Island residents. More recently, the Lawrence Livermore National Laboratory (LLNL) has developed the Accelerator Mass Spectrometry capability for environmental and radiobioassay samples.

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 be extremely sensitive and capable of detecting ^{239}Pu in urine specimens at the microBq per liter range in a reliable and accurate manner. A second study, funded by the DOE, LANL, LLNL and the University of Utah, was initiated in 2001 to determine the advances in the mass spectrometry technology for radiobioassay applications in terms of detection capability, bias, precision and nuclide selectivity. This study concluded that cutting-edge measurement capability is more closely associated with a laboratory's expertise rather than the technology used. A third study was initiated in 2003 to determine the state-of-the-art for isotopic uranium measurements from urine samples. Evaluation samples have been sent to participating laboratories at this time.

In 1999, the "Workshop on Standards, Intercomparisons and Performance Evaluations for Low-Level and Environment Radionuclide Mass Spectrometry and Atom-Counting" was held at NIST. The workshop was well-attended by national and international experts in mass spectrometry at various government and commercial facilities and covering a multitude of applications including international performance evaluation programs, radiobioassay, environmental and marine research, nuclear site remediation and facility effluent analyses. The end product of the workshop was the development of a needs report for long-lived radionuclide reference materials for mass spectrometry by application and a summary of the current capability and practicality of existing mass spectrometers by type.

At the request of the US Army in 2000, reference materials were developed by the New Brunswick Laboratory and the DOE Radiological and Environmental Sciences Laboratory for a mass spectrometry calibration / quality assurance program. The reference materials developed were synthetic urine samples containing certified amounts of depleted uranium at various concentration levels.

Action Items:

1 – Conduct a third intercomparison study to evaluate the capability of various mass spectrometric techniques for the assay of isotopic uranium in synthetic urine specimens.

2 – Provide leadership and program manager to initiate a national program for physical and consensus standards, intercomparisons, and performance evaluations that will serve the needs of the emergency response and cleanup radionuclide mass spectrometric community.

3 – Update the needs of the mass spectrometry community and provide a formal needs report upon which program funding can be based and obtained.

4 – Develop a NIST capability to produce and verify long-lived radionuclide reference materials for various mass spectrometric applications.

5 – Develop a NIST capability to enable NIST traceability for a national performance evaluation program for the testing of laboratories engaged in the MS analysis of environmental and bioassay samples for radionuclides.

6 – Continue research and development of radiochemical separations, source and ionization optimization, and pulse counting optimization.

Resources Required:

1 – One-half full time employee or contractor equivalent at NIST for program development and administration and the development of the necessary technical capability for the funded program.

2 – Enhanced TIMS, RIMS, ICP-MS and MS-MS radionuclide metrology capabilities at NIST.

3 – Sufficient and dedicated laboratory facilities and resources to conduct the analytical portion of developed programs.

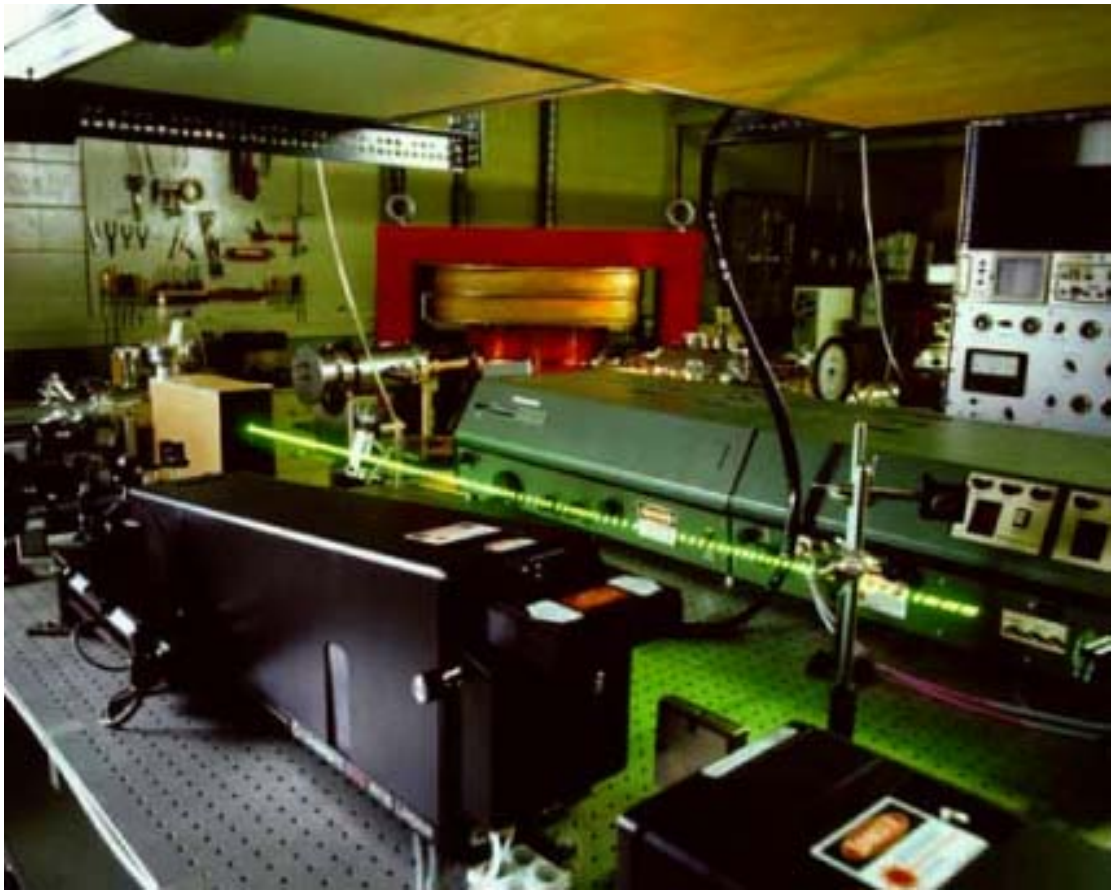

Figure B.9.1 – Resonance ionization mass spectrometry (RIMS) system (courtesy of NIST Ionizing Radiation Division)

NOTE: In the CIRMS "Second Report on National Needs in Ionizing Radiation Measurements and Standards," published in October, 1998, this MPD appeared as MPD B.4. A new MPD number has been assigned, MPD B.9, to avoid confusion with MPD B.4 that had appeared in the first CIRMS "Report on National Needs in Ionizing Radiation Measurements and Standards," published in January, 1995, that covered a different topic, and MPD B.4 in the second report.

MPD C.3.3: INTERCOMPARISON TRANSFER STANDARDS FOR NEUTRON SOURCE CALIBRATIONS

Objectives: Develop and promulgate protocols for the use of thermoluninescent dosimeters as intercomparison standards that will be effective on a national and international level.

Appraise and report on the reliability of other intercomparison transfer standards and instruments for neutron source calibrations.

Background: 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.

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.

Typical personnel dosimeters have been irradiated under nearly identical conditions at NIST and PNNL. The results of this study are presently being evaluated. Follow-on experiments will determine optimal reader parameters and appropriate irradiation and readout protocols for use of the Thermoluminescent Dosimeter (TLD) system as transfer standards in intercomparison measurements and for proficiency testing of calibration laboratories seeking accreditation by National Voluntary Laboratory Accreditation Program (NVLAP) for dosimetry. When the irradiation conditions have been established the study needs to be extended to additional US and foreign laboratories to fully evaluate the technique. Results will be published and presented at a CIRMS meeting or CIRMS workshop.

Additional efforts will be undertaken to evaluate the use of instruments including 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 (ED) 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.

Through participation in ISO standards efforts NIST personnel and personnel from other US secondary laboratories (PNNL) will seek optimization of intercomparison methods and seek international standardization to ensure worldwide consistency of neutron dose measurements to radiation workers throughout the world.

NIST and PNNL will be primary participants in these efforts. Other laboratories and vendors will be involved as the electronic dosimeter evolves and in the intercomparisons on a volunteer basis. The laboratories will need to perform experimental irradiations, establish a pool of transfer dosimeters/instruments and develop capability to analyze and tabulate the results.

Action Items:

1 – Evaluate and establish protocols for the use of thermoluminescent dosimeters (TLDs) to be used in intercomparison studies and as transfer standards.

2 – Extend the results of the TLD program to involve non-US laboratories.

3 – Evaluate neutron survey meters, ion chambers and electronic dosimeters for their reliability as transfer standards for general measurement of neutron dosimetry.

4 – Optimize the intercomparison and standardization protocols for neutron dosimetry through participation in international standardization efforts (ISO) so that they become applicable on a world-wide basis.

Resource Requirements:

1 – The neutron calibration program will require one person-year per year over the next three-year time frame and approximately $150,000 for equipment and supplies.

2 – Funding must provided for personnel to track and participate in international standards efforts. It is estimated that this will require 5-10% of an individual's effort per year plus travel costs $30,000 per year.

MPD C.4.3: IMPROVEMENTS FOR IN-VIVO AND IN-VITRO RADIOBIOASSAY METROLOGY

Objectives: Improve the consistency of measurements for internal radioactivity depositions in humans resulting from occupational or natural exposure.

Develop techniques that can detect and measure lower concentrations of radionuclides in organs and soft body tissues.

Background: Non-invasive in-vivo and in-vitro radiobioassay (whole-body and organ counting, and urine, feces and tissue radioanalysis, respectively) of personnel working with radionuclides or materials with potential radioactive contamination is a primary method dosimetrists employ for routine occupational monitoring and accident assessment.

The variability among "homemade" and de facto reference phantoms can account for up to an 80% difference among measurement laboratory results [Kramer, G. H., Loesch, R. L., and Olsen, P. C. "The Second International *In-Vivo* Intercomparison Program for Whole Body Counting Facilities by Canadian and United States Agencies;" **Health Physics** 80(3), 214-224 (2001)]. Measurement comparability and consistency can be ensured through calibrations based on national standard realistic human-surrogates (calibration phantoms). In addition, site-specific (organ specific) quantitative assessment requires new measurement technology and 3-D tomography. A solution to the problem of measurement differences is the continued development of technological and measurement quality assurance bases for quantitative site-specific in-vivo radio-bioassay. This is a recommendation of the International Workshop on Standard Phantoms for In-Vivo Radioactivity Measurements [**Health Physics**, **61**, 893 (1991)].

Similarly, the variability of in-vitro radiobioassay measurements is largely due to sampling heterogeneity and non-equilibrium of chemical yield monitors with the analytes of interest during sample preparation. While sample heterogeneity problems may be improved by taking larger or more samples, problems of completely equilibrating the chemical yield monitors with the analyte in the sample is largely dependent on the chemical speciation of the analyte. For example, refractory plutonium particles in the lung or in fecal samples could be underestimated by 15-50 percent if insufficiently aggressive dissolution methods were used. Even in cases where the analyte is easily solubilized, precision of analysis of radionuclides in synthetic urine

and fecal test samples is of the order of 10-15 percent (Wu, et.al., BERM Conference Proceedings). To improve these capabilities, there is a need for the development of new reference materials and traceable Proficiency Testing programs to continue to evaluate and improve the measurement community's capabilities.

In 1995 ANSI N13.30, "Performance Criteria for Radiobioassay" was adopted by US DOE, and incorporated into the DOE Laboratory Accreditation Program. DOELAP has been performing accreditations of US National Laboratories since 1998. This Standard defined testing criteria for minimum performance expected of an operating radiobioassay laboratory, including test samples and bias and precision limits. The standard has been the basis for the development of an international standard by ISO. There are, however, measurement scenarios and techniques that were not considered by the ANSI N13.30 working group, such as refractory plutonium in fecal and lung samples and the current use of sensitive mass spectrometers. Future progress is expected on the completion of the calibration phantom standards, dose calculation standards, introduction and validation of new radioanalytical methods, revision of the ANSI N13.30 standard, and the continuation of accreditation programs.

The benefits of this initiative to personnel safety include: comparable and improved quality of dosimetry assessments; assessment of dose to individual critical organs; transferable dosimetry histories for employees; and 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 Health Physics Society Standards Committee (HPSSC), work has been performed on materials development, modeling and computational validation studies have been performed and work is continuing 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.

Considerable progress has been made in the area of in vivo metrology. Three ANSI standards on phantoms are nearing completion; a computational method for the validation of counter calibrations was completed and progress is continuing on improved phantom materials and methods of phantom comparisons.

In-vitro radioanalytical methodologies for easily solubilized radionuclides has been established within the metrology community and much of this capability is being tested under the DOE Laboratory Accreditation Program for Radiobioassay and the NIST Radiochemistry Intercomparison Program. Furthermore, radioassay of radionuclides in human tissues have been established for post-mortem biokinetic modeling and litigation resolution. The US Transuranic and Uranium Registries and other similar research laboratories around the world require certified reference materials for: a) method validation, b) data comparability, c) quality control, and d) defensibility. NIST SRMs 4351 (Human Lung), 4352 (Human Liver), and 4356 (Ashed Bone) have been issued to satisfy these needs. In general, the overall bias and precision of the participating laboratories meet the ANSI N13.30 criteria. What has not been tested, however, is the ability to adequately measure refractory radionuclides such as the high fired plutonium and Class Y forms of the radionuclides in bioassay samples.

Action Items:

1 – Develop calibration systems and quality assurance protocols for radionuclide-labeled organ and phantom surrogates.

2- Facilitate comparison of calibrations with standard phantoms to surrogates in the DOE phantom library and to real animal/human exposures in order to improve measurement techniques and measurement consistency.

3 – Develop 3-D tomography and related computational methods for improved definition of organ/tissue modeling.

4 – Evaluate long-term massic activity stability of radionuclides in synthetic urine and fecal test samples.

5 – Develop certified high fired plutonium performance test samples.

6 – Extend bioassay accreditation programs, possibly through the HPS accreditation program, beyond the current DOE RESL program.

Resource Requirements:

1 – A cumulative expenditure of approximately $3million over the next three-year time frame will be needed to sustain and properly coordinate efforts at NIST, LLNL, the Bureau of Radiation and Medical Devices (BRMD), RESL and PNNL on new phantom materials, ANSI and international standards, techniques for assessing homogeneity and content of phantom inserts, and Monte Carlo calculations.

2 - An investment of 1 FTE to evaluate the long term stability of the synthetic urine test samples, and develop the reliable production and certification of refractory plutonium in bioassay test samples.

3 – Investigation of extending accreditation efforts to sectors other than DOE will require a minimum of 20% of a person year of effort.

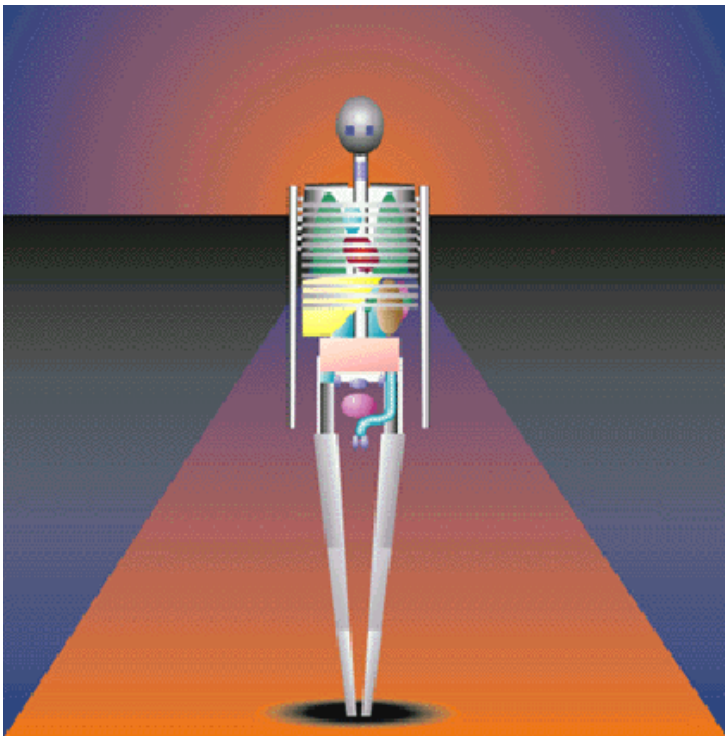

Figure C.4.3 – Computer phantom used for modeling personnel radiation exposures

MPD C.17.2: IMPROVED RADIATION MEASUREMENT INFRASTRUCTURE FOR OCCUPATIONAL RADIATION PROTECTION

Objective: Improve the occupational radiation measurement infrastructure through the development and implementation of measurement standards and accreditation programs on a national and an international level.

Background: 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 US 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 the new

standard ISO/IEC 17025 (cancels and replaces ISO/IEC Guide 25), which establishes general criteria for laboratory performance. Through meetings and information exchange CIRMS makes continual progress in this area; with recent incorporation of ISO/IEC Guide 25 into the programs. The stage must be set to upgrade to ISO/IEC 17025. 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 International Electrotechnical Commission (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 International Commission on Radiological Protection (ICRP).

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.

Currently a national effort is underway to accredited accrediting organizations using ISO Guide 58, "Calibration and Testing Laboratory Accreditation Systems-General Requirements for Operation and Recognition (Revision of ISO/IEC Guides 38, 54, and 55)". This effort needs to be reviewed by the affected programs to determine the value to their efforts. CIRMS can assist by providing the technical expertise needed to provide an orderly acceptance of these efforts. Operating the accreditation programs through an organization that is accredited based on internationally accepted criteria will provide significant benefits: improve acceptance of the programs by the regulators and the customers (an accreditation certificate has not been universally recognized as an indicator of program quality), and provide international acceptance of the accreditation programs.

CIRMS acts to facilitate the relationship of users, program developers, and NIST in the development and implementation of accreditation programs and must continue this effort. CIRMS acts to identify needed studies to improve the technical basis for the programs and assist with the implementation. CIRMS has had information exchanges for the two revisions of the dosimetry accreditation program (based on revisions to ANSI N13.11) that have occurred in recent years.

CIRMS members need to meet with national/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 US practice and US 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, information exchanges at the CIRMS annual meetings can fill this need. Special meetings to address implementation of standards and accreditation programs will be needed. An ad hoc working group should be formed through CIRMS to study the pattern testing/type testing philosophy and make recommendations.

Action Items:

1 – Identify those standards that are needed to support the radiation measurement infrastructure for the protection of occupational workers.

2 -- Participate in the development of standards, including providing supporting data such as conversion coefficients, on a national and an international level.

3 – Seek broader national and international acceptance of existing laboratory accreditation programs, improve upon their inter-comparability and provide guidance and assistance as needed.

Resource Requirements:

1 – Funding to facilitate annual meetings to monitor the progress on the above.

2 – 1/2 person-year per year over a three-year timeframe to study the evolving methodologies and criteria for personnel radiation protection and accreditation of laboratory protocols.

MPD C.19.1: NIST TRACEABILITY FOR LOW DOSE -RATE CALIBRATIONS

Objective: Promote the development of low-dose rate calibration reference fields for NIST and the development of accreditation programs for low dose-rate calibrations.

Background: In 1997, the Nuclear Regulatory Commission (NRC) published regulatory requirements and regulatory guidance relative to the specific radiological criteria for the decommissioning of lands and structures. These criteria apply to the decommissioning of most types of facilities licensed by the NRC and the Agreement States. Having been adopted in final form, these criteria are to 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 and could pose technical challenges for determining compliance using existing radiological survey methods. In 1995, guidance documents were written by the NRC (e.g., NUREG-1507) 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.

In the spring of 1999 a workshop was held to discuss calibration of dose rate meters for low levels of activity such as one must deal with during environmental monitoring, emergency response, waste management, decommissioning, recycling and transportation of items. In addition, protection specialists are becoming more concerned with conducting work area surveys at increasingly lower dose rates. The meeting was sponsored by CIRMS, the Conference of Radiation Control Program Directors (CRCPD), NIST and DOE. Field measurements (more cost effective than laboratory measurements) are receiving increased emphasis resulting in significant concern over traceability and accreditation among organizations using different instruments and techniques. Comparability of measurements is important to avoid costly re-measurement efforts, to ensure data defensibility, and to provide a high level of confidence to the public as to the quality of data generated in radiological survey

work. In addition, low dose rate traceability will benefit environmental measurements performed at most nuclear facilities. At present, NIST does not provide direct calibration measurements at such low levels, but it is possible to extend capability to these lower levels. Traceability of such low-level measurements to national physical standards is not available on a national level. K & S Associates have established low-dose rate fields and the required procedures. In addition, the HPS has developed accreditation criteria and by working through the National Physical Laboratory (United Kingdom) has accredited K&S Associates. However, it is important that NIST establish the required reference fields to facilitate the accreditation process.

NIST plans to extend the present reference dose rates available for gamma-rays down to lower levels in the 1mR/h range. As a first step, a new improved track system has been build that allows positioning ionization chambers at a given distance from a Cesium-137 (^{137}Cs) source. As a second step NIST is currently in the process of upgrading the ^{137}Cs beam irradiator that will be used for this project. Upon completion of the upgrade, characterization of the reference fields will follow using the new beam irradiator and track system. These reference fields will be used as part of a future calibration service.

Action Items:

1 – Develop NIST capabilities to support low dose-rate calibrations and testing.

Resource Requirements:

1 – One person-year over the next 1-2 year time frame is needed at NIST to complete development of a capability to perform calibrations and proficiency tests at low dose rates (background to ~10mR/h). Needed equipment costs should be <$75,000.

2 – An additional 1/4 person-year per year will be needed to continue promotion and development of procedures for the extension of present dose rate calibration capabilities to low dose rates

MPD C.20.1: IMPLEMENTATION OF SUPPORT FOR PERSONNEL DOSIMETRY PROFICIENCY TESTING PER ANSI N13.11

Objective: Support the implementation of proficiency testing under criteria developed for ANSI N13.11.

Background: Proficiency testing of dosimetry systems is required by both the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC) for dosimetry of record for radiation workers. In the past the criteria and needs for the NRC and DOE have been different and covered in different standards; American National Standards Institute (ANSI) N13.11 for the NRC and an internal DOE standard for DOE. The most recent revision of ANSI N 13.11 incorporates both agencies' requirements thus providing a single set of criteria for proficiency testing in the US for dosimetry systems. The testing requires carefully defined criteria for sources, geometries, irradiation procedures, conversion coefficients, etc. in order to provide a fair test of the candidate dosimeters. It is important that the users, the standards laboratories and the standard developers exchange information to provide a realistic and equitable basis for testing. As the proficiency testing evolves it is important to identify needed studies to improve the technical basis for the program and assist with the implementation. CIRMS has had information exchanges for the two revisions of the dosimetry accreditation program (based on revisions to ANSI N13.11) that have occurred in recent years. It is important that such exchanges continue to occur and identify this need in a separate MPD will provide more visibility for support of the proficiency testing program.

Action Items:

1 – To implement revisions of the ANSI N 13.11 standard, the following must be addressed:

a) Methods for dealing with multiple sources of exposure.

b) Sharing of test data to validate the new test categories in order to shorten the pilot test phase.

c) Ways to deal with the thermal neutron component of exposures.

d) Methods for dealing with low dose exposures and fading.

e) Testing at high energies for both neutrons and photons.

Resource Requirements:

1 – Periodic meeting must be held to follow through on the details involved in implementing ANSI N 13.11. Funding for such meetings should be <$50,000.

2 – To address the issues highlighted above requires one person-year of support over the next three year time frame. Such support can be divided between NIST and the proficiency test laboratories during the implementation of the new criteria. Subsequently, continuing support of 1/4 person-year will be needed.

MPD E.1.0: EMERGENCY RADIOLOGICAL RESPONSE

Objective: Develop a national network of radiological analytical laboratories capable of responding to the radiological analytical needs required in the aftermath of a terrorist attack involving radiological materials.

Background: Homeland Security Presidential Directive/HSPD-9 on Defense of the United States Agriculture and Food (January 30, 2004) calls for the development of nationwide laboratory networks for food, veterinary, plant health and water quality that integrate existing federal and state laboratory resources, are interconnected and utilize standard diagnostic protocols and procedures.

Several federal agencies are currently developing emergency plans to respond to terrorist attacks involving radioactivity. An integral component of these plans involves utilization of the existing networks of radiological laboratories to analyze clinical and environmental radioactive samples. Radiological laboratory analysis is critical to providing decision-makers with data to make life saving, economic and critical resource preservation decisions.

The Department of Energy (DOE), the Environmental Protection agency (EPA), and the Food and Drug Administration (FDA) each maintain or are compiling a catalog on the capability and capacity of radiological laboratories serving their needs. In addition, there are ongoing efforts by the EPA and Department of Homeland Security (DHS) to develop a catalog of the capability and capacity of federal and state environmental radiation monitoring programs.

Some government agencies have established mission driven objectives and mission specific laboratory response networks. However, there is an additional need to maintain an integrated national and international network of laboratories that are available to respond quickly to acts of radiological terrorism. This network, to be called the Radiological Emergency Analytical Laboratory Network (REALnet), would encompass all entities capable of performing radiological measurements, and would provide a mechanism to facilitate and coordinate the collection, distribution and exchange of information. Shared information could include the capability, capacity and availability of laboratories in the network to respond to a specific need, as well as the results of laboratory visits and inspections, laboratory points of contact, performance testing results and acceptance criteria. Detailed information about the network and ability to quickly identify resources best suited to the needs of the response to a specific threat or

emergency could be made available over a secure Internet connection to designated federal, state and local government agencies. When an incident occurs, REALnet would also coordinate the distribution of samples, collection of measurement results, assess the results and communicate findings to decision makers.

The REALnet framework will be used to identify and promulgate the use of existing standards and best practices and will identify needs for new standards in such areas as sample collection and storage, contamination control, analytical methods, and communication of analytical results. In addition, REALnet would provide a mechanism to identify common network needs such as management tools (Geographic Information System – GIS and Database Applications, etc.), member laboratory requirements (inspections, accreditation, performance testing, etc.), training, funding, and incentives for network participants. These common needs can be jointly identified, developed, shared and communicated, thus eliminating duplication or overlap of efforts currently expended by the various agencies.

Action Items:

1 - Develop a detailed plan for the contents and the structure of the REALnet database, based on the recommendations from the breakout session of the Radiation Protection subcommittee during the 13th Annual meeting of CIRMS, October 2004, and from the focused workshop taking place immediately at the conclusion of the annual meeting.

2 - Develop criteria for a performance testing program of radiological laboratories that would assure the competence of these laboratories and help identify their capabilities when a radiological emergency occurs and the laboratories' response is required.

3 - Support acceptance of the REALnet concept by promoting the program elements to the emergency management.

Resource Requirements:

1 – An appropriate web server, software and computer services for the first year of developing the database - $300 000.
2 – Ongoing support by computer services - $100 000 annually.
2 – Full-time staff for program administration - $300 000 annually.
3 – Contract for a performance testing program meeting REALnet and DHS needs - $400 000 annually.
Total: $ 1.0M for first year, $ 0.8M subsequent years.

MPD E.2.0: PERFORMANCE CRITERIA FOR SERVICE LABORATORIES PERFORMING PERSONNEL RADIATION EXPOSURE DOSE ASSESSMENT USING SOLID MATRIX BIOLOGICAL MATERIALS

Objective: Develop performance criteria for service laboratories performing personnel radiation exposure dose assessment using solid matrix biological materials (such as teeth, bone, lens, etc.).

Background: Electron paramagnetic resonance (EPR) and optically stimulated luminescence (OSL) methodologies are being applied to determine personnel radiation exposure dose assessment using solid matrix biological materials (i.e., teeth, bone, lens, etc.). Recent international inter-comparison studies demonstrate harmonization of dental enamel EPR radiation dosimetry using an "internal standard" method by which the extracted tooth enamel solid matrix biological material is subjected to added *ex vivo* radiation dose to determine an individual sample specific radio-response that is then used along with the baseline measurement to estimate the exposure dose. A similar approach can be applied using other solid matrix biological material and either EPR or OSL detection methodologies.

Optimization of parameters to recording EPR spectra of dental enamel for dose assessment include the use of software programs to fit results to model spectra and correction factors for differing geometric sizes of tooth structures. Errors of dose determination can be influenced by a number of parameters including sample masses.

A critical need in this area is performance criteria for service laboratories performing dose assessment to permit harmonization of protocols and reporting results with error estimates among laboratories.

Action Items:

1. Convene a panel of internationally recognized EPR and OSL experts in radiation dose assessment to establish a harmonized consensus protocol or to adopt an existing internationally accepted published protocol.

2. Establish performance criteria for service laboratories performing personnel radiation exposure dose assessment using solid matrix biological materials (i.e., teeth, bone, lens, etc.) using EPR or OSL detection methodologies.

3. Advance the use of the harmonized consensus protocol and performance criteria for dose assessment of solid matrix materials and conduct a consensus building workshop to cover this topic.

Resource Requirements:

1. A minimum of 2 person-years per year over the next three year time period is required to launch into these objectives. Some partnerships between NIST and industry are warranted in this area.

2. Funding to support convening of expert panelists for regular meetings to develop the consensus protocol and performance criteria as well as sponsoring the consensus workshop and proceedings.

MPD E.3.0: PERFORMANCE CRITERIA FOR SPECIALIZED TEAMS SUPPORTING MEDICAL RESPONSE DURING NUCLEAR AND RADIOLOGICAL EMERGENCIES INCLUDING TERRORISM INCIDENTS

Objective: Develop performance criteria for specialized teams supporting medical response during nuclear and radiological emergencies including terrorism incidents at the pre-hospital (deployable) or hospital level.

Background: The medical response in nuclear and radiological emergencies should involve concerted efforts from various specialized teams (i.e., decontamination, bioassay, radiopathology, biodosimetry, hematology, dosimetry, and radiation epidemiology). The functions of these various specialized team are being defined in an International Atomic Energy Agency (IAEA) guideline for generic procedures for medical response during nuclear and radiological emergencies and other sources. These teams require appropriate expertise and are typically equipped with specialized equipment, supplies, and software tools for performance of their defined functions.

The present threat of radiological terrorism acts involving potential mass casualty incidents dictate an urgent need to enhance national medical preparedness. The composition of the members of these specialized teams likely will be derived from both the civilian and federal sector.

A critical need in this area is performance criteria for these specialized teams supporting medical response during nuclear and radiological emergencies to provide critical consensus guidance. These performance criteria need to be developed consistent with an all-hazard approach used by first responders.

Action Items:

1. Convene a panel of internationally recognized experts of specialized medical response teams supporting medical responses during nuclear and radiological emergencies in order to establish harmonized consensus protocols or to adopt existing internationally accepted published protocols.

2. Establish performance criteria for these specialized teams supporting medical response.

3 Advance the use of the harmonized consensus protocols and performance criteria for these specialized teams and conduct a consensus building workshop to cover this topic.

Resource Requirements:

1. A minimum of 4 person-years per year over the next four year time period is required to launch into these objectives. Partnerships between NIST and other personnel from federal agencies are warranted in this area.

2. Funding to support convening of expert panelist for regular meetings to develop the consensus protocol and performance criteria as well as sponsoring the consensus workshop and proceedings.

Note A

FOUNDATION FOR PUBLIC AND 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 big-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 US 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 Department of Defense (DOD) have prepared a document entitled "Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM) that addresses 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, the Department of Commerce (DOC) and the Department of the Interior (DOI) for radioanalytical services (Multi-Agency Radiation Laboratory Protocols Manual - MARLAP) related to plant decommissioning and site remediation activities was published in December 2004. A few of the key elements of MARLAP include the development of Measurement Quality Objectives for a project, the use of the

performance-based method selection process, the requirement for method validation and the initial and continuous monitoring of the method's / laboratory's performance through various quality control and/or performance evaluation (PE) programs. The application of the MARLAP recommendations will require NIST to become more proactive in the development of standard reference materials for a variety of nuclides and matrices and to become involved in the traceability aspects of the federal agency and commercial measurement assurance programs.

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. Beryllium-10 has been used to understand aspects of glaciology and climatology (climate records, hello- and 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 has 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 sediments 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 involves 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 pBq 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, including homeland security applications. While there are many radioanalytical methods, detection systems, and calibration standards available, current metrology needs require rapid reduced-cost turnkey 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. In

the near future, PERP will focus its attentions on three general metrology areas: (a) Standard Reference Materials; (b) analytical / instrumental methods development and validation; and (c) measurement assurance programs.

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 various environmental, radiological monitoring and bioassay matrices. The matrices may include processed and ground waters, soil, sediment, dried vegetation, air particulate filter media, concrete, asphalt, metal, glass, marble, and synthetic urine, feces, body organs and whole bodies. The radioactive sources may vary from single nuclide tracers or mixed radioactive standards to ultra-low level (10^6 atoms) for atom counting methods. These Standard Reference Materials would be instrumental in establishing traceable derived performance testing materials for site-specific remediation projects, such as the remediation projects for the DOD and DOE, remediation of nuclear power plant facilities, and homeland security consequence management response/cleanup, and for use in measurement assurance programs. Such sources are essential for technical defensibility when contractors and regulators must declare when a remediation or removal program has been completed.

Analytical / instrumental methods development and validation: There are many needs for a new generation of instrumentation and analytical methods 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, thermal ionization mass spectrometry and accelerator mass spectrometry) is crucial. Furthermore, new technologies and radioanalytical techniques are now needed for homeland security interdiction/prevention and rapid response consequence management decision making.

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.

Note B

FOUNDATION FOR OCCUPATIONAL RADIATION PROTECTION MPDS

The work environment must be fully characterized in order to protect the health of radiation workers. At the present time the cumulative number of radiation workers in the nuclear industry distributed among DOE facilities and in the various and diverse licensees of the NRC or the states are over one million workers. Since radiation cannot be detected by the human senses, workers depend upon measurement tools and techniques to control their exposure to radiation. Planning and controlling the 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 in the public 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 dosimetry and bioassay results constitute the legal record of the worker's exposures. However, measurements made with reliable instrumentation prior to entry and during work in a radiation area are essential in minimizing worker's exposures and in complying with the principal of keeping radiation exposures As Low As Reasonably Achievable (ALARA). ALARA is used throughout the industry as a guiding principle for the control of worker's radiation exposures.

In recent years we have seen the increasing availability of sophisticated instruments and dosimeters resulting from the increasing sophistication and miniaturization of electronics. However, performance evaluations and intercomparisons have shown the response characteristics remain dependent on such factors as the environmental conditions, the dosimeter processor, and the quality of the calibrations. The reliability of the measurements has not improved with the increasing sophistication of the measurement tools. In the case of personnel dosimeters, recognition of the deficiencies led to the establishment of accreditation programs for dosimetry processors. This program has significantly improved the overall performance of dosimetry processor's in the US. However, maintaining these improvements requires continued diligence.

Although new technology provides us with more and more information, today the work environment requires more accurate measurements at lower dose rates. A large fraction of the workers continue to be exposed to radiation in the medical, nuclear power, and research industries, but must meet regulatory demand for lower worker exposures and improved control of the radiation environment. Today we see many

workers involved in environmental cleanup activities and these workers encounter a different radiation environment than one would expect in a typical work environment.

Expansion of accreditation programs, improvement of calibration techniques and capabilities, improvement of the control or understand the measurement techniques, and development of new measurement techniques results in improved measurement reliability. In turn, improved measurement reliability assists in protecting the occupational radiation worker and the public. The improved reliability of the measurements and control of the radiation environment increase confidence in the nuclear industry. This will improve public acceptance of the industry and lead to its continued viability.

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. The Industrial Applications and Materials Effects (IAME) subcommittee differs in that it deals primarily with the use of radiation in industrial processes, in contrast to applications related to effects on humans. Four sources of radiation used within the industrial community are taken into account:

Accelerated Electron Beams
X-rays Generated from Electron Beams
Gamma Rays from Radioactive Isotopes
Neutron and Mixed Field Sources

ACCELERATED ELECTRON BEAMS

Many industrial applications rely upon high current, high dose rate electron beam accelerators that provide ionizing radiation to enhance the performance and/or market value of materials or processes. It has been estimated that there are in excess of 1000 such electron beam accelerators now in use in industry. Research to support some of these industrial uses is sometimes carried out using low current accelerators, such as the historic Van de Graaff generators or pulsed linear accelerators.

Electron beam accelerators in the 100 to 300 kV voltage 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 or segmented filaments in parallel and have been made at up to three meters in length. The limited penetration of

300 keV electrons (approximately 430 μm or 17 mils in unit density material) 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 amps (A) 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. Such low voltage accelerators are mostly used by major corporations capable of marketing the high production output.

Recently, very low voltage accelerators with energies in the range from 70 to 150 keV but with substantial beam currents have been developed for coatings and thin film applications. These units are more compact and should be more affordable for modest sized industrial applications. Even at these very low voltages, there is sufficient beam penetration (80 μm or 3 mils) to cure inks, pigmented coatings, and adhesives and to crosslink thin gauge polymeric films. Some emerging areas of market interest have been in the use of low-voltage accelerators for surface sterilization of food packaging materials and air purification as well as for the curing of coatings that are in compliance with US Food and Drug Administration regulations for direct food contact. In these emerging areas of interest, dosimetry and dose determinations are becoming more important. Low-voltage accelerators are also being explored to implement in-line sterilization of packaged medical devices.

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. The crosslinking of wire and cable jacketing is an accepted industrial practice with formulations having been, for the most part, converted to non-halogen containing flame-resistant materials. The crosslinking of wire and cable jacketing is often the first industrial use of irradiation processing espoused in developing areas, as there is need for such materials to support the development of infra-structure to transmit electricity.

While lead shielding has been used for accelerators up to 0.8 MeV, shielding for mid and 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 (National Council on Radiation Protection and Measurements – NCRP Publications, Bethesda, MD). The maximum voltage attained at these high beam currents (up to 100 mA) is 5.0 MeV (but at reduced amperage), which implies beam penetration of 1.9 cm (0.8 inches) for unit density materials (per equal entrance – equal exit surface dose).

Many other significant industrial operations rely upon mid-range, high current accelerators as part of manufacturing processes. For example, tire companies (Bridge-stone, Goodyear, Michelin, for example) 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 (Cryovac Division of the Sealed Air Corporation) and heat recoverable tubing (Raychem, part of Tyco Electronics, a subsidiary of Tyco International) 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 some use in the sterilization of medical devices.

For the most part, the higher voltage, high current accelerators are used for market applications wherein their higher beam penetration is of consequence (10 MeV giving 3.9 cm electron penetration in unit density material). These markets include medical device sterilization, food irradiation and some curing of the matrix resins used in fiber reinforced composite plastics. Despite angst over public acceptance, food irradiation is supported by a continuing series of positive results for providing a safe and effective means of eliminating hazardous food contaminants. Regulatory barriers are continually being overcome. More recently, accelerators with high beam currents and high energy (10 MeV) have become available. Heretofore, much high voltage work depended upon low current linear accelerators (linacs).

No specific needs pertaining to accelerator design or development are addressed in this report. For a majority of low and mid voltage electron beam industrial applications, product properties and performance requirements and not dosimetric parameters dictate the needed exposure to ionizing radiation. 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 that 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.

X-RAY IRRADIATION

When electrons impinge upon a material target, x-rays are emitted. With the development of high current, high energy (5.0 to 10 MeV) accelerators, the known inefficiencies of energy conversion from accelerated electrons to x-rays has been found to be overcome by substantial increases in available beam current. While only ~6-10% of electron energy is converted to x-rays, with high current sources the x-ray output is sufficient to make x-ray processing a viable alternative to other technologies.

X-ray processing is being used to "sanitize" sacks of mail for the US Postal Service to eliminate any possible biohazard contamination (see Appendix B-c). X-ray processing systems designed around high current, high-voltage accelerators are under investigation for use in food irradiation as well as medical device sterilization. With x-ray penetration being comparable to that of gamma, these devices that are electrically powered are of interest so that there is no concern over the transport and use of radioactive materials. While emerging as a viable technology, no specific measurement needs are perceived for x-ray usage in that the dosimetry systems developed for electron beam and gamma processing can also be used for x-ray sources.

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 cobalt-60 (^{60}Co) radiation sources. In years past, there had been a modicum of interest in the use of Cesium-137 (^{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 ionizing radiation from an electron beam, 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.

- The ability to be scaled down for research purposes with a readily available installed base of research scale systems.
- The ability for large scale commercial facilities to increase product capacity by commensurate increases in the cobalt source.
- Lower dose rates of approximately 10 kiloGrays per hour (kGy/h), in contrast to electron beam dose rates of 10 kGy/s.

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 October 1998, **Second Report on National Needs in Ionizing Radiation Measurements and Standards**, five Measurement Program Descriptions (MPDs) were outlined in the "Industrial Applications and Materials Effects" section:

D.3.1 Radiation Hardness Testing and Mixed-Field Radiation Effects.
D.4.1 Neutron Dosimetry for Reactor Pressure Vessel Surveillance.
D.5 Medical Device Sterilization
D.6 Pollution Prevention (P2)
D.7 Food Irradiation

MPD D.3.1 and MPD D.4.1 were revisions of corresponding MPDs that appeared in the first CIRMS "Needs Report" published in 1995. These have been revised again and brought up-to-date for this report and are presented as MPD D.3.3 and MPD D.4.3 and reflect the status and needs as they now exist in 2004. There is a continuing need for long-term commitment in these critical areas of interest. Likewise, MPD D.5.2 is a revision of the MPD on "Medical Device Sterilization" as is MPD D.7.2 on "Food Irradiation." All four of these MPDs now reflect accomplishments since the previous "Needs Report" and address future needed actions and resource requirements.

MPD D.6 on "Pollution Prevention" in a previous report, the second report issued in 1998, had been dropped. However, the growing use of low voltage electron beam accelerators has contributed to compliance with Clean Air Act requirements. As such this radiation process has become accepted as a "green" or environmentally friendly process and so recognized by regulatory authorities. The unique demands for more reliable dosimetry in the low-voltage electron beam area are presented in a new MPD, D.8.0. The limited penetration of these beams poses new demands on dosimeters.

Despite numerous positive demonstration projects involving radiation processing to remediate, disinfect or detoxify sludge, wastewater, and soil, none of these approaches has gained acceptance in the engineering community or proven commercial viability within the United States. A major industrial installation of the use of ionizing radiation to remove the acid rain contributors of sulfur dioxide (SO_2) and nitrous oxides (NO_x) from the stack gases of a 100 MW, coal fired electric generating station is operating continuously on a full-time bases in Pomorzany, Poland, relying upon funding obtained through the International Atomic Energy Agency. Capable of handling 300,000 cubic meters of gas emissions per hour, this plant not only eliminates the SO_2/ NO_x but converts these to a useful by-product of mixed nitrates that can be used as fertilizer.

As a result, the Industrial Applications and Materials Effects sub-committee proposes four revised and up-dated MPDs in this report and the addition of one new one dealing with some specific needs of the fast growing low-voltage accelerator community.

D.3.3 Radiation Hardness Testing and Mixed-Field Radiation Effects
D.4.3 Neutron Dosimetry for Reactor Pressure Vessel Surveillance
D.5.2 Medical Device Sterilization
D.7.2 Food Irradiation
D.8.0 Low-voltage Electron Beam Dosimetry

MPD D.5.2 and MPD D.7.2 note the diversity of dosimetry methods that have been developed and recognized by industrial organizations and associations, including many that are recognized on an international basis by adoption by the International Standards Organization (ISO).

MPD D.3.3: RADIATION HARDNESS TESTING AND MIXED-FIELD RADIATION EFFECTS

Objective: Provide radiation hardness testing capabilities for space environments.

Background: 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 National Aeronautics and Space Administration (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 US 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.

There are but a few facilities capable of providing the radiation fluxes needed for these and other emerging needs, predominately in aerospace programs.

- The Naval Surface Warfare Center/Carderock Division at the Naval Research Laboratory (NRL) operates a 3 MeV tandem NEC PELLETRON that has provided

neutron beams of appropriate energy (from 0.2 to 4 MeV), and fluence values (from 1 x 10^{12} to 1 x 10^{15} cm^{-2}) vital for testing electronic components used in space-based applications. Very tight geometry, small sized objects can require 30 to 40 hours of continuous accelerator operation to achieve a desired total integrated neutron fluence. To attain more typical neutron fluence requires an average 8 to 10 hours of irradiation.

Presently efforts are underway to provide suitable low-energy neutron beams ranging from thermal energies to a few keV. These beams will be used not only for radiation hardening applications but also in the areas of imaging, dosimetry development and for Boron Neutron Capture Therapy, BNCT in collaboration with researchers from the FDA. 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, the Applied Physics Laboratory (APL) in Laurel, MD and the University of Maryland (both the College Park and Baltimore County campuses) make this a very attractive facility.

NRL also maintains expertise in measuring and quantifying the loss of performance electronic devices as a function of dose, particle type, flux, etc. This expertise can be called upon to characterize changes in electronic device performance due to radiation hardening.

- Sandia Laboratory has initiated the use of microbeams to investigate problems involving radiation hardness testing. Of particular interest has been difficulties with boron silicate glass as used as microchip insulators in which neutron-induced reactions in the boron leads to upsets from the charged particle reaction products. The Naval Surface Weapons Center (NSWC) Carderock Division also has a microbeam capable of evaluating materials for radiation hardness down to 100 microns.

- Rensselaer Polytechnic Institute's Gaerttner LINAC Laboratory has a 70 MeV accelerator that can also be used in radiation hardness testing.

- Kent State University in its joint partnership at NEO Beam has a high current 5 MeV Dynamitron accelerators that has been used in solar panel evaluations.

- Boeing maintains a Radiation Effects Laboratory (BREL) that is equipped with a 5 to 10 MeV linear accelerator, a 2.8 MeV Dynamitron accelerator and a neutron beam source. Boeing is capable of directing all three sources to a single point in order to conduct irradiation experiments with combined fields.

At its 9th Annual Meeting, CIRMS conducted a focused workshop on "Dosimetry for Radiation Hardness Testing: Sources, Detectors and Computational Methods." Input from that workshop has been incorporated above.

Action Items:

1 – Maintain and upgrade the tandem accelerator facility at the Naval Surface Warfare Center for conducting radiation hardness testing and support for other facilities capable of performing radiation hardness testing.

2 – Assure that a budget of at least three person-years per year is committed to providing research and service to the organizations and institutions involved in radiation hardness testing.

3 – Promulgate the capabilities of the Naval Surface Warfare Center**,** Sandia Laboratory, Rensselaer Polytechnic Institute Gaerttner Laboratory, Kent State University NEO Beam facilities and Boeing BREL radiation hardness testing facilities throughout US industry and government and enhance interaction between university capabilities and these existing institutions.

Resource Requirements:

1 – With facilities in place, a sustained commitment to a minimum of three person-years per year is needed over the next three-year time frame.

2 – On going capital expenditures of <$500,000 will be needed to sustain the up-grading of facility capabilities to meet emerging demands over the next three years.

MPD D.4.3: NEUTRON DOSIMETRY FOR REACTOR PRESSURE VESSEL SURVEILLANCE

Objective: Sustain NIST traceable neutron dosimetry protocols for the nuclear power industry.

Background: 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 (US NRC) 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." 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 US NRC 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 computational 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 computational 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.

MPD D.4.3 on Neutron Dosimetry for Reactor Pressure Vessel Surveillance requires long term commitment and sustained involvement. In the past (September, 1996), NIST hosted a public meeting in which representatives from the commercial nuclear-electric-generating industry shared their ideas and concerns regarding USNRC regulatory guide DG-1053, "Calculational and Dosimetry Methods for Determining Pressure Vessel Neutron Fluence," with members of the NRC staff and the principal authors of the document. Two new ASTM standards have been adopted that address the use and application of standard neutron fields and engineering benchmarks for verification and validation of reactor vessel surveillance analysis: E-2005 "Standard Guide for Benchmark Testing of Reactor Dosimetry in Standard and Reference Neutron Fields" and E-2006 "Standard Guide for Benchmark Testing of Light Water Reactor Calculations." An ANS standard dealing with the determination of RPV neutron fluence has also been developed. Several research endeavors are continuing; in particular, NIST is conducting an investigation to assess the adequacy of the ENDF/B-VI iron inelastic scattering cross section for neutrons undergoing deep penetration.

As of November, 2004, periodic validation of radiometric dosimetry employing certified fluence standards from reference neutron fields as recommended in RG 1.190 (formerly DG-1053) is no longer considered a priority by the US NRC or the reactor industry.

Action Items:

1 – Maintain NIST capabilities for neutron dosimetry.
2 – Enhance NIST's interaction with the nuclear power industry, which itself allocates substantial manpower resources to conform to NRC regulations.

Resource Requirements:

1 – With facilities and protocols in place, NIST requires a sustained commitment of a minimum of one person-year per year over the next three-year time frame.

MPD D.5.2: MEDICAL DEVICE STERILIZATION

Objective: Promulgate NIST traceable empirically verified protocols for gamma and electron beam dosimetry used in medical device sterilization.

Background: 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 radiation sterilization in their device manufacturing processes. 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) and in doing so requires a complete protocol of record keeping, traceability, written procedures and the like.[1] For sterilization, the FDA has accepted the standards and guidelines established by the Association for the Advancement of Medical Instrumentation (AAMI – see www.aami.org). These along with specific dosimetry test methods and procedures developed by the ASTM International (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.

Radiation, mainly in the form of gamma rays emitted from Cobalt-60 sources, has been used for more than thirty five years as an alternative to ethylene oxide and autoclave technology. The radiation sterilization process must be carefully monitored in order to assure that no harmful chemical species have been developed inside the device package due to the sterilization process and that the devices are sterile. The first one of these issues has been addressed by extensive radiation chemistry studies on the chemical compounds used in the manufacturing of medical devices, while the second one is guaranteed through appropriate dosimetry methodology. The processing parameters that are usually verified during the radiation sterilization of medical devices as part of the dosimetry methodology are:

- Dose, expressed in kiloGrays
- Dose rate, expressed in kiloGrays per unit time

- Irradiation temperature
- Three dimensional (3D) dose distribution and modeling

Most radiation sterilization of medical devices is carried out in gamma irradiator facilities. However, the use of electron accelerators in this technology is steadily increasing, adding a new series of requirements for the dosimetry techniques used to control the process. In this respect, 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.

AAMI has published eight documents pertinent to radiation sterilization and is in the process of publishing additional ones.[2-9]

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.[10-27] ASTM is also in the process of publishing a new "Standard Practice for Blood Irradiation Dosimetry."

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.

Currently several dosimetric techniques have been adopted by the medical device industry for use in the quality control of radiation sterilization. These techniques rely on the use of a dichromate solution,[16] alanine pellets, [20] polymethylmethacrylate (PMMA) dosimeters, [13] radiochromic dye films[12] and alanine coated films. In the Second Report on **National Needs in Ionizing Radiation Measurements and Standards** prepared by the CIRMS Science and Technology Committee that issued in October 1998, a series of needs were identified in order to support the radiation measurements activities in this area. As then stated, the following national needs were defined:

1. Establish cost-effective and timely procedures for NIST calibrations of routine dosimeters.

2. Encourage the use of enhanced dosimetry techniques.

3. Establish a national reference beam for high dose rate electron beam output.

4. Foster the development and implementation of real-time-dosimetry methods.

The importance of the issues underlying these stated needs was reviewed at the CIRMS meeting held in October 2000. Regarding the first issue, 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 this segment of the industrial community. A proposed solution was to establish a cooperative program between NIST and an independent organization that could cofund and provide personnel who could use NIST facilities to perform the necessary calibrations. The implementation of the remote-via-internet ESR-alanine calibration technique (e-calibration) will help to alleviate this problem. Once this technique is implemented in a service facility, all the labor related work will be carried out on site. NIST calibration and certification will be handled via internet connection to a NIST based system that will, while connected, take control of the on site test instrument to verify readings and calibrations. The implementation of this technique will also impact on the second need noted above. However industry training and the establishment of NIST traceable protocols will be needed for the establishment of this new technique. A continuing effort on the part of the NIST is needed to provide the expertise to maintain and quickly respond to the calibration needs of involved laboratories. Such sustained support is also needed during the transition of industry to this more precise technique as well as to assist in demonstrating e-calibration's applicability in other areas of radiation processing.

Initially, most radiation sterilization of medical devices was performed using gamma rays. However nowadays more and more sterilization of medical devices is being performed using electron beams. Typically these electron accelerators operate at beam currents between 5 and 50 mA either as a continuous beam or at very high pulse rates. As a result, these high current electron accelerators produce dose rates in excess of 10 kGy per second. Consequently, there is a need to develop high dose-rate electron beam calibration capabilities at NIST to correspond to the industry use of high dose-rate accelerators for medical device sterilization.[28] To expedite the calibration of a high current electron beams, NIST should collaborate with academic partners (for example, Kent State University or the University of Maryland) to establish a calibration service of dosimeters at high dose rates.

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. Two types of real time dosimeters have been developed thus far: the "Monitorad" and the "Cdose". The use of

some other systems like transistor dosimeters has been proposed. Transistors imbedded in product or packages could themselves provide remote read-out of dose. The potential of these electronic devices as well as other potential candidates as real-time radiation dosimeters warrants continued study. Establishment of real-time dose monitoring will reduce the operator dependent measurements of transfer materials, such as conventional dosimetry systems, which are read independent of the actual process. Additional resources will be needed to explore the applicability of these real-time dosimeters over a broader range of irradiation parameters, and, in particular, over extended dose rate intervals, notably the high dose rates from electron accelerators.

Other needs surfaced during the CIRMS October 2003 meeting:

- Low voltage electron beam dosimetry
- Modeling of dose distribution in heterogeneous packages
- Three dimensional dose distribution and dose mapping
- Harmonization of standards

Commercial electron accelerator facilities operate at a wide range of acceleration voltages or potential. Beam voltages as low as a few hundred keV have been used for many years in coating and surface modification of materials using very high current levels to produce economically attractive throughputs. It is conceivable that lower voltages could be used in the future to sterilize medical products packaged in thin geometries. While NIST has done a commendable job in refurbishing a low voltage electron accelerator and using it for the calibration of dosimeters at low electron voltages, for its national standards programs NIST must avail itself of state-of-the-art high current, low voltage equipment.[28] Suitable candidates as radiation dosimeters for these possible low voltage applications are the thin radiochromic dye film dosimeters already available through the Risø National Laboratory in Denmark and the film alanine dosimeters from the Eastman Kodak Company. There is a need to characterize these presently available dosimeters at low voltage, high beam current electron accelerator conditions as well as to support the development of new dosimetric materials which could be used at low voltage levels.

Modeling and the measurement of dose distributions or three dimensional (3D) dose mapping are an integral part of the qualification process for an irradiated product. Computer codes like ITS and PENELOPE (both available through Oak Ridge National Laboratory Radiation Safety Information Computational center) are readily available to calculate the dose distribution inside a product box and to "visualize" the effect of boundaries and interfaces between dissimilar materials in terms of their density, which

are irradiated in the same box, as in the case of surgical blades. Dose distributions are also useful in determining positions of minimum and maximum dose inside the box and to guarantee that all the medical devices inside an irradiated box will attain the minimum required dose for sterilization. NIST support is essential in providing this type of modeling and computer code service to the medical device industry using radiation sterilization.

There are several organizations that provide technical support to the radiation sterilization industry: the US FDA, AAMI, ASTM, NIST, and the National Physical Laboratory in the United Kingdom (NPL), the Risø National Laboratory in Denmark, and the Radiation Processing Simulation and Modeling User Group (RPSMUG) among others. These organizations provide diverse services to the radiation sterilization industry: dosimeter calibrations, standard experimental techniques for the calibration and use of dosimeters and facilities, regulations and recommendations. There is a need to harmonize the efforts of all these organizations in such a way as to provide a concerted support to the medical device sterilization industry, which, as it grows, becomes more multi-national and international in scope. Such harmonization process could be carried out through the IAME subcommittee of CIRMS.

Action Items:

1 – Establish more formal collaboration amongst the FDA, AAMI, ASTM E10.01, NPL, Risø, PTB, ISO, RPSMUG and NIST on international dosimetry protocols. One-person year over a three year time frame is required for such coordination efforts.

2 – As had been done in the European Union,[29] conduct an industry wide gamma and electron beam dosimetry inter-comparison with medical device sterilization facilities to establish the overall variability in dose measurement amongst these facilities and to promote the improvement in dose determination accuracy and the use of a uniform methodology to perform dosimetry measurements. This will require one-person year over a two year period.

3 – Empirically verify the alanine dosimetry technique so that it can be recognized as a method of test with verifiable precision and bias statements. At the same time broaden the acceptance of a NIST dosimetry e-calibration service. A continuing effort of at least one person-year over the next three years will be needed to continue the transition to alanine dosimetry and to demonstrate its applicability in more diverse product forms.

4 – Develop low voltage high dose-rate electron beam calibration capabilities at NIST and in collaboration with an existing facility to correspond to industry use of high dose-rate accelerators for medical device sterilization. A one-half person-year will be needed to start the needed electron beam calibrations and to establish protocols for use of such a facility as a NIST qualified reference beam.

5 – Fully characterize the two real-time dosimetry systems currently available in the market ("Monitorad" and "Cdose") and examine the use of transistors as real-time dosimetry systems as well as other possible semiconductor and optoelectronic devices. A one-half person-year effort over a three-year time frame will be required.

6 – Establish the means, protocols, and assist in establishing industry standards for correlating dose distribution predicted by modeling and calculation techniques with empirical dosimetry data. One-half person-year over a three year time period is required.

Resource Requirements:

1 – NIST acquisition of or a formal collaboration with a of a state-of-the-art high beam current, high dose-rate electron beam accelerator to serve as a national reference source.

2 – Acquisition of a high current, low voltage electron accelerator in order to provide dosimetry calibrations with energies below 300 keV.

3 – A minimum of three person-year commitment per year to accomplish the above noted action items.

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[9] ANSI/AAMI/ISO 11137 (1994) – “Sterilization of Health Care Products – Requirements for Validation and Routine Control -- Radiation Sterilization”
[10] ISO/ASTM 51205:2002 – “Practice for Use of a Ceric-Cerous Sulfate Dosimetry System”
[11] ISO/ASTM 51261:2002 – “Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing “
[12] ISO/ASTM 51275:2004 – “Practice for the Use of a Radiochromic Film Dosimetry System”
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[18] ISO/ASTM 51539:2002 – “Guide for Use of Radiation-Sensitive Indicators”
[19] ISO/ASTM 51540:2004 – “Practice for Use of a Radiochromic Liquid Dosimetry System”
[20] ISO/ASTM 51607:2004 – “Practice for Use of an Alanine-EPR Dosimetry System”
[21] ISO/ASTM 51608:2002 – “Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing”
[22] ISO/ASTM 51631:2003 – “Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations”
[23] ISO/ASTM 51649:2002 – “Practice for Dosimetry in an Electron-Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV”
[24] ISO/ASTM 51650:2002 – “Practice for Use of Cellulose Acetate Dosimetry Systems”

[25] ISO/ASTM 51702:2004 – "Practice for Dosimetry in Gamma Irradiation Facilities for Radiation Processing"
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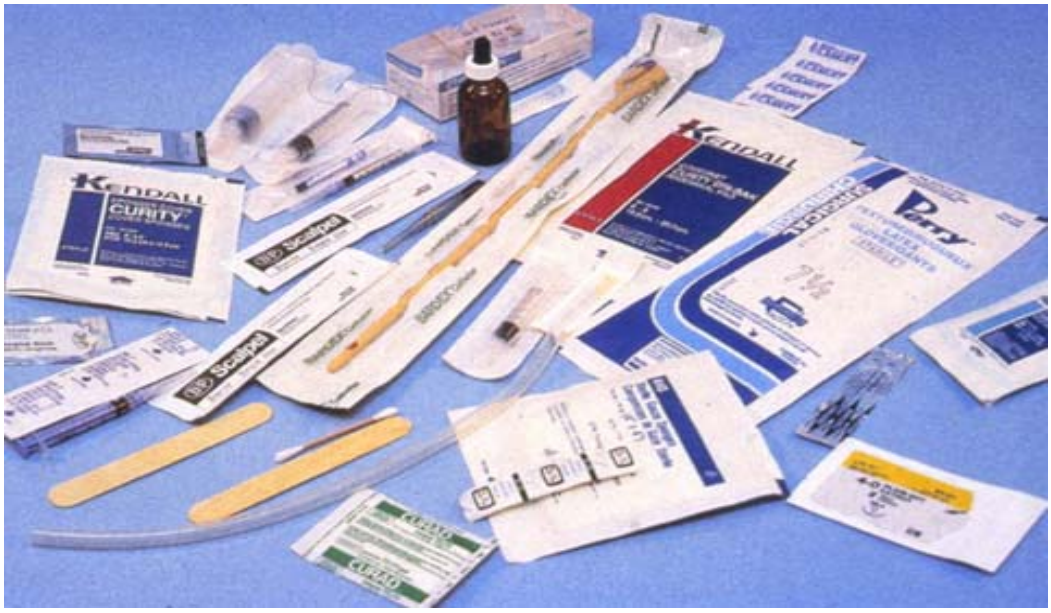

Figure D.5.2 – Diversity of medical products that are radiation sterilized

MPD D.7.2: FOOD IRRADIATION

Objectives: Establish NIST traceable protocols to calibrate and verify dosimetry for all aspects of the food irradiation process.

Establish protocols to quantify the biological effects of food irradiation.

Background: Increased concerns about the overall safety of the food supply chain in North America have, in the United States, empowered the US Food and Drug Administration (FDA) and the US 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 Listeria, Salmonella and Escherichia coli contamination, especially in red meats, have spurred support for these measures from food industry groups. Thus, there is a renewed interest in the use of ionizing radiation as a method to control pathogens in food products. (See: www.food-irradiation.com – for technical details.)

The food irradiation process is an important technology for the treatment of foods contaminated with such pathogenic microorganisms, and methods to improve the effectiveness of treatment plans have obvious social and economic benefits. Significant benefits to food include the inactivation of these microorganisms, the inhibition of many enzymatic processes, and the use of irradiation as an alternative to chemical treatments for disinfestation which rely upon toxic substances that can become environmental pollutants.

The efficacy, minimal effect on nutritive value and general safety of irradiating food has been demonstrated over and over again throughout the past several decades. The World Health Organization (WHO) has long been on record as supportive of this method for processing 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 have been few commercial sources whose primary business is the irradiation of food products. Despite considerable misconceptions about consumer reactions, there has been a generally favorable response to irradiated food products, which provide safe and less perishable items to grocery stores. 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. However, that attitude is also changing.

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 being conducted at several academic institutions. The Canadian Irradiation Centre (Ville de Laval, Quebec), which operates in cooperation with the Universite du Quebec, Institut Armand-Frappier, the Canadian Department of Agriculture's Food Research Centre (St. Hyacinthe, Quebec) and Kansas State University (Manhattan, Kansas), all operate ^{60}Co gamma irradiation facilities. Iowa State University (Ames, Iowa) operates a 10 MeV electron beam center and Texas A&M University also operates a 10 MeV electron beam with x-ray capability on its campus at College Station, Texas.

In the food irradiation process, a main objective is to minimize overdosing and/or underdosing the product while maximizing microorganism death under acceptable conditions in order to prevent any deterioration of a food's nutritive value. This is very important. Overdosing the product may cause serious quality degradation, while underdosing is more serious since pathogens may survive and spoilage may result. Injured but potentially viable microorganisms may contribute to an underestimation of the surviving population and an overestimation of the process effectiveness. Thus, it is of paramount importance, regardless of the source of ionizing radiation, but perhaps more so with the newer modality of x-ray processing, to develop protocols to assure that the minimum (Dmin) and maximum (Dmax) dose ranges are attained. Biological kill under specific process conditions has to be empirically established.

Exposure of foodstuff to ionizing radiation initiates a complex series of physical, chemical, and biological changes that may result in microorganism endurance and/or quality deterioration of food. The biological effects of food irradiation arise because of damage to the individual microorganism. When ionizing radiation passes through matter, atoms are randomly ionized and excited. These atoms then initiate numerous chemical reactions that when passing through a cell produce DNA damage. Thus, ionizing radiation kills a microbial cell by inducing a small amount of molecular damage in a cell component critical to survival: DNA. Irradiation initially creates various types of DNA damage and competition to repairing and converting potentially repairable forms of DNA damage into irreversible forms of damage affect the probability of a cell surviving irradiation. Insight into these more fundamental biochemical mechanisms will complement observations dealing with individual microorganisms and strengthen the basic understanding of the food irradiation process.

In the case of food irradiation, injured but potentially viable microorganisms may contribute to an underestimation of the surviving population, and an overestimation of the process effectiveness. Due to differences in their physiological state and changes in their characteristics, they may pose a problem regarding to detection. The effect of dose rate on the inactivation of microorganisms is complex. High dose-rates from electron accelerators have been found to be efficient in killing microorganisms as have lower dose-rates from gamma sources and x-ray generators. The relationship between dose-rate, dose, and exposure time versus survival fraction for microorganisms warrants further study. Understanding how microorganisms respond to irradiation will allow the prediction and mitigation of survival of pathogens to irradiation treatment. This, in turn, will translate into a significant improvement in food irradiation as a decontamination technology thus ensuring the safety of our food supply. Food processors, public health officials and consumers will use this new knowledge to maximize the safety, nutritional value, and desirability of irradiated foods.

In order to guide industry in the practical implementation of the food irradiation process, two sub-committees of the ASTM International (ASTM), Subcommittee E10.01 on Dosimetry for Radiation Processing and Subcommittee E10.06 on Food Irradiation 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 eleven ASTM standards providing information about food irradiation, some of which have attained international recognition through the collaborative agreements between ASTM International and the International Standards Organization (ISO):

[1] ISO/ASTM 51204:2004 – "Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing"
[2] ISO/ASTM 51261:2002 – "Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing "
[3] ISO/ASTM 51431:2002 – "Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing"
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[5] ISO/ASTM 51940:2004 – "Guide for Dosimetry for Sterile Insect Release Programs"
[6] ASTM E 2381-04 – "Guide for Dosimetry in Radiation Processing of Fluidized Beds and Fluid Streams"

[7] ASTM F 1355-99 – "Standard Guide for Irradiation of Fresh Fruits as a Phytosanitary Treatment"
[8] ASTM F 1356-99 – "Standard Guide for the Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms"
[9] ASTM F 1640-03 – "Standard Guide for Packaging Materials for Foods to Be Irradiated"
[10] ASTM F 1736-03 – "Standard Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms"
[11] ASTM F 1885-04 – "Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms"

In addition, one new standard is underdevelopment pertaining to irradiated food products: ASTM "Standard Guide for the Irradiation of Prepackaged Processed Meats and Poultry Products To Control Pathogens and Other 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 high 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. Micronutrients (vitamins and minerals) are affected to about the same degree as they are when treated by 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 are also of importance in gaining consumer acceptance of this process for improving the safety of the food supply.

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

Food irradiation procedures spell out minimum or 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.

High volume gamma facilities have been designed for processing fresh and frozen meat and poultry products. These may attain a max to min dose uniformity ratio of less than 1.5 for typical product configurations.

It is well known that bremsstrahlung, or x-rays generated by the impingement of high-energy 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. Recently, Ion Beam Applications (IBA) submitted a petition to the US FDA requesting an increase in the maximum x-ray energy from 5.0 MeV to 7.5 MeV for use with food processing within the United States. The theoretical and experimental evidence submitted with this petition indicate that the proposed increase in energy will be safe from the standpoint of public health, so the company is optimistic about its approval in the near future. The use of higher energy and/or higher beam power will make the x-ray processing of foodstuffs more economically viable (See Figure 7.2).

Action Items:

1 – Catalog current available information on the food irradiation process now available from the USDA, FDA, WHO and other resources and post links to web sites on the CIRMS web page. In so doing, establish a network of collaboration amongst food industry technologists, the irradiation processing industry and academia, to develop a database covering the different levels of sensitivity (injury, recovery, and repair) of food pathogens to the effect of physical chemical variables (pH, temperature, , food composition, nutrition, oxygen, dose and dose rate). The complex array of presently available information on the Internet warrants a focused coordination. Such focus could be brought with apropos links on the CIRMS web-site.

2 – Conduct a workshop with the food processing industry and those involved in food irradiation to explain the implications of dose on the reduction and elimination of bioburden.

3 – In collaboration with processors currently engaged in irradiating food, assess various dosimetry techniques and prepare a consensus report on a preferred dosimetry method of test for establishing dose for irradiated food and related packaging materials and on dose-mapping techniques that can be used for verifying depth-dose penetration in the broad spectrum of densities encountered in food products.

4 – Include aspects of food packaging materials irradiation in such report, such as work being conducted within the Society of the Plastics Industry (SPI) in its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC) on irradiation effects on packaging materials for food that will be irradiated in its package.

5 – Extend the use of the NIST Internet based e-calibration dosimetry service for food irradiation.

6 – Utilize complementary methodologies being developed for dosimetry metrology for medical device sterilization (MPD D.5.2).

7 – Using Monte Carlo calculations, determine the dose distributions for heterogeneous food product packages, such as boxes of chicken wings with their bones for the different modalities which can be used as sources for ionizing radiation, gamma, electron beam and x-ray. Confirm such determinations with empirical dosimetry studies, giving emphasis to the precision of the Dmin and Dmax ratios attainable per mass or type of package of food product.

8 - Catalog available information on the characterization of the occurrence and magnitude of a recovery phenomenon for microorganisms following irradiation and, at the research level, investigate the ability to mathematically model the degree of lethal and potentially-lethal injures to micro-organisms due to irradiation, noting such factors as dose and dose rate.

Resource Requirements:

1 – A specific person, possibly within a government or university laboratory, is needed to coordinate and gather information on all of the various aspects of food irradiation, including developments in understanding the fundamental biochemistry underlying of the effects of ionizing radiation on food, as well as implications on dosimetry calibration services posed by the food irradiation process. This should be a full time effort, not taken on as an additional work assignment. A minimum of one person-year per year over the next three years time interval is needed.

2 – Retain outside consulting services as needed to supplement NIST commitments in this area.

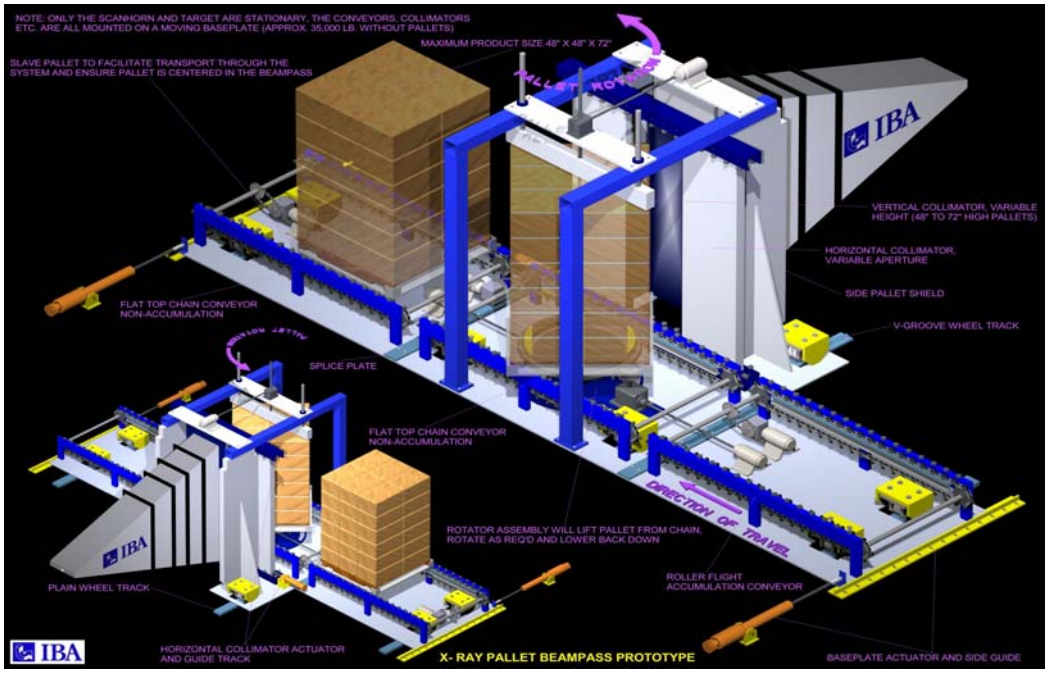

Figure D.7.2 – Rendition of x-ray irradiation of full pallet loads of foodstuffs (courtesy of Ion Beam Applications/MDS Nordion)

MPD D.8.0: LOW-VOLTAGE ELECTRON BEAM DOSIMETRY

Objective: Using industrial high-current, low-voltage electron accelerators confirm primary dosimetry protocols based on calorimetry and correlate with apropos transfer dosimetry films.

Background: High-current, low-voltage (300 kV or less), self-shielded electron beam (EB) accelerators represent the fastest growing segment of the industrial accelerator market. Such equipment is used in the curing or drying of inks, coatings and adhesives, in the manufacture of laminates and in the production of metallized and heat-shrinkable food packaging films. When used to cure or crosslink liquid inks or coatings containing near-zero Volatile Organic Compounds (VOCs), such low-voltage equipment enables users to comply with and often exceed the regulations derived from the 1990 Amendments to the Clean Air Act and to do so with enhanced operational and electrical efficiency.

Within recent years, more compact low-voltage, high-current and lower cost accelerators have been developed, thereby improving the cost-effectiveness of what had heretofore been considered capital intensive equipment. Such scaled down linear or segmented filament equipment and innovative modular beams have also found considerable acceptance for use at lower voltages, down to 80 kV, and yet with high beam currents. Beam penetration, even at such low voltage, is sufficient to dry or cure, for example, printing inks. Being electron beams, there is no sensitivity to pigmentation or colorants in inks or coatings as with, for example, the use of ultraviolet radiation. This limited beam penetration, however, poses challenges to the use of more traditional dosimetry systems and their related materials and equipment.

Concurrent with these developments in equipment has been the growing market interest in the use of low-voltage EB for applications that must comply with government regulations. Low-voltage units are being evaluated for use in the surface sterilization of containers to be used for foodstuffs. Such self-shielded units are also being used to cure or crosslink coatings that can be used in direct food contact and remain in compliance with US Food and Drug Administration (FDA) extractable limitations. The use of EB in the manufacture of heat-shrinkable food packaging films is also finding low-voltage equipment to meet the manufacturing demands of such products. The resultant film products too must comply with FDA regulations.

A methodology and needed equipment for doing primary dosimetry based upon calorimetry has been developed and reported on by the Risø National Laboratory in Denmark. Using a laboratory unit centered upon a modular, low-voltage, high-current electron beam, Risø has used thermal input into a specially designed calorimeter and converted such data into the standard dose unit, the Gray.

Risø has then also calibrated thin film radiochromic dosimeters (its 17µ B3 films) with its calorimetry data to develop calibration curves for said film. Readings of these films were made with an operator-independent RisoeScan system that utilizes a flatbed optical scanner and specialized software to express response in terms of dose.

In parallel, polymeric films coated with thin films of alanine have been developed by the Eastman Kodak Company, their BioMax™ alanine dosimeter films. The instrument manufacturer Bruker Biospin has modified its e-scan™ electron paramagnetic resonance (EPR) reader to accommodate reading of such films. The e-scan system too is operator-independent and has a built-in reference to correct readings for changes in laboratory environmental conditions, such as temperature and humidity. In gamma and higher voltage EB dosimetry, the e-scan system has been linked electronically, either via telephone or Internet hook-up, to a reference device at the US National Institute of Standards and Technology (NIST).

Action Items:

1 – At another recognized national laboratory, such as NIST, use an industrially comparable low-voltage, high-current EB unit, to duplicate and inter-compare results obtained using a primary dosimetry technique, calorimetry, with those obtained at Risø.

2 – Develop calibration curves for thin film dosimeters that can be read with minimal operator dependence for both alanine coated and radiochromic films, said films being made on a continuous basis to a prescribed coating thickness.

3 – Conduct a broad-based inter-laboratory comparison of low-voltage EB dosimetry based on operator-independent reading systems using alanine coated films and/or controlled radiochromic films. Use such data to develop empirically based precision and bias information.

4 – Elevate the procedures used to characterize low-voltage EB dosimetry into a recognized "Standard Method of Test" as acknowledged by a standards organization such as ASTM International.

Resource Requirements:

1 – A national laboratory, such as NIST, needs to procure a high-current, low-voltage electron beam which, being self-shielded, should be <$150.000.

2 – Approximately two-person years of technical time are needed divided amongst at least two national laboratories in order to develop the needed calibration data and to conduct industry based inter-laboratory studies.

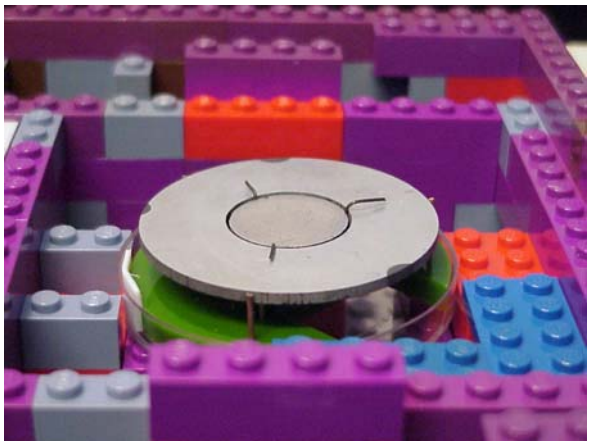

Figure D.8.0a – Low-voltage electron beam calorimeter (courtesy of Risø National Laboratory, Denmark)

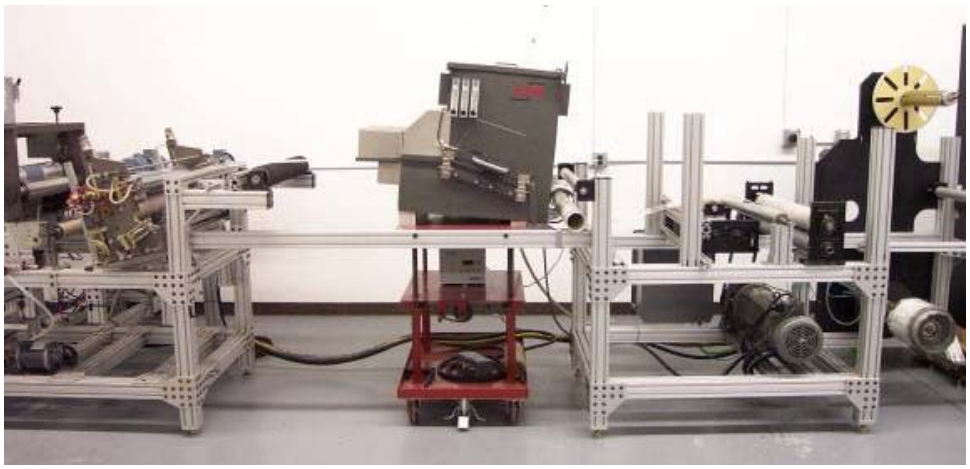

Figure D.8.0b – Low-voltage electron beam on coating pilot line (courtesy of Advanced Electron Beams, Incorporated)

F. COMPUTATIONAL MPDs

INTRODUCTION TO COMPUTATIONAL MPDS

The use of mathematical modeling underlies many of the diverse uses involving ionizing radiation. The Ionizing Radiation Division in the Physics Laboratory at the National Institute of Standards and Technology (NIST) has been a pioneer in the development of codes widely used in such modeling. These codes are used in medical, industrial and radiation-protection applications. At NIST, Monte Carlo calculations for dosimetry are cross-checked with ionizing radiation measurements. NIST graphite-wall cavity-ionization chambers serve as the national standard for air-kerma (radiation exposure). Recent wall corrections obtained from Monte Carlo calculations will adjust air-kerma standards world-wide by up to about 1%. Accurate measurements and calculations of absorbed dose play a significant role in industry, ensuring adequate dose in radiation processing (medical device sterilization, bioagent deactivation, etc.). In medical applications, assessing dose rate accurately is critical to effective treatment planning and fulfilling regulatory constraints.

Recognizing this broad-based use of computational methods, a new category of Measurement Program Descriptions is introduced relative to computational needs. In this area, one new MPD is presented:

F.1.0: Improvements to Computational Methods for Radiation Dosimetry

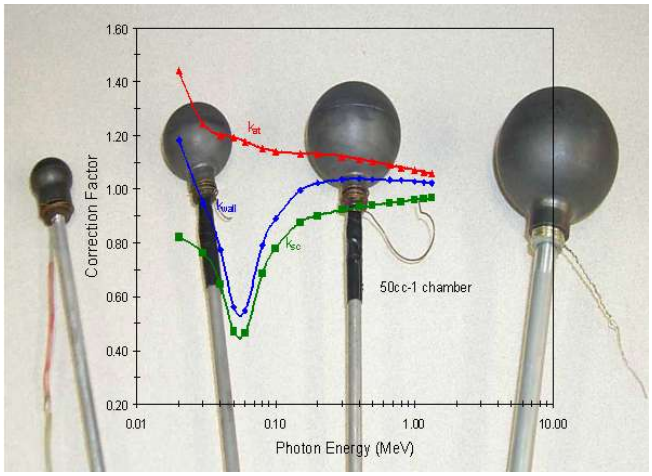

Figure F.1.0 – NIST graphite-wall air-ionization chambers and their wall corrections derived from Monte Carlo calculations (courtesy of NIST Ionizing Radiation Division)

MPD F.1.0: IMPROVEMENTS TO COMPUTATIONAL METHODS FOR RADIATION DOSIMETRY

Objective: Improve the basic radiation-interactions cross-section information and the mathematical algorithms and codes to support the critical role of computation in radiation dosimetry for standards and for diverse applications.

Background: Computations have increasingly become a vital part in the chain of steps that relate measurement to dose or kerma. Dosimetric calculations are rooted in comprehensive evaluations of data that describe the basic physical interactions of radiation with matter. These evaluations are then utilized by computer codes that simulate the macroscopic measurement system under consideration, modeling the system in all necessary detail. These computer codes can be deterministic, but more often employ the Monte Carlo technique of particle transport. In addition to their vital role in the standards and measurement process, such codes find increasing use in radiation protection, medical, industrial and security applications involving dosimetry.

Computations have always been a part of the chain of steps that link measurements made with devices such as a calorimeter or an ionization chamber to fundamental quantities such as absorbed dose or air kerma. In recent years, advances in computing systems and in calculation methodology have enabled such computations to play an increasingly vital role in this chain. In fact, calculations have recently begun to supplant some experimental methods in determining the factors representing departures from idealizations employed in the relationship between measurements and standards. As an example, one may look at the air-kerma standard for high-energy gamma rays. Measurements performed using graphite-walled air-filled ionization chambers in the field of a Cobalt-60 (^{60}Co) source have long been used to determine a standard. However, in order to obtain an accurate standard, a host of departures from cavity theory must be taken into account through the use of multiplicative correction factors. In the past, measurements were devised to obtain many of these factors. Beginning in the late 1980's, a group from the National Research Council laboratories in Canada was able to show that a number of these corrections could be obtained using direct simulations. In fact, these calculations show that some of the experimental methods that had been utilized were flawed, leading to deviations at the one percent level. Recently, the National Institute of Standards and Technology's (NIST's) Radiation Interactions and Dosimetry group applied the simulation method to correct for a number of factors in the high-energy gamma-ray air-kerma standard. One of these

factors was the correction for the interactions of the gammas in the wall of the graphite ionization chambers that are employed in the establishing the standard. Previously, an experimental method that relied upon varying wall thicknesses was used to extrapolate the wall thickness to zero. The Monte Carlo calculations provided new wall corrections, affirming that, in the case of the NIST chambers, the experimental method was inaccurate up to the one percent level due to the nonlinearity in the response as the wall thickness decreases.

All computational methods, whether deterministic or Monte Carlo or some simpler approximation, rely on accurate and comprehensive physical data to describe the interaction of radiation with the underlying media of which the system under consideration is composed. The data in use at present comes from a variety of sources. In the case of electron and positron physics, the stopping power, range and radiation yields are generally taken from the 37th report of the International Commission on Radiation Units and Measurements (ICRU). This data set in turn relies heavily on NIST critically evaluated databases. These databases provide a description of the effects of many collisions on a particle's motion. The effects of individual collisions on the motion of the electron or positron are not as well-understood. Often, the cross-sections utilized to describe these interactions are taken in their high-energy limit or to lowest order in the interaction. Such descriptions are often effective in describing the gross behavior of the particle far from ionization thresholds but fail to give valid results at lower energies or for the details of the process. In fact, only recently have some aspects of the basic three-body problem of the ionization of atomic hydrogen by electron impact been solved. The situation for ion-atom data is somewhat worse, as comprehensive data for the multi-collision process exists only for a few light projectiles. There are alternative approaches for such data, with differences among the data sets. It is more difficult to obtain cross-sections for individual ion-atom interactions than for the interaction of electrons or positrons with atoms. In the case of photon-atom interactions, the photon is annihilated in these interactions. Data representing individual interactions of photons with atoms are fairly extensive. Most of these datasets represent a compromise, made three decades ago, between accuracy and detail on the one hand and the ability to provide consistent and comprehensive tabulations on the other. The increase in computational power since that time enables one to take a second look at these processes in order to decide whether greater accuracy or more detail is warranted. In fact, efforts have been underway at NIST to upgrade photon-scattering databases.

While deterministic (discrete-ordinates) methods are quite powerful in solving the radiation-transport equations in some cases, the Monte Carlo transport method is more

often chosen to simulate radiation transport. The reason is that it is often difficult to describe a realistic system and its boundary conditions in a suitable manner for use within a deterministic method. Many different Monte Carlo transport codes exist for use in radiation transport. The variety of codes proves useful as the codes tend to specialize in different areas. Monte Carlo codes for the transport of photons and electrons are of critical importance in dosimetry. There are a number of codes available that simulate photon and electron transport. The electron-gamma shower code (EGS4) from the Stanford Linear Accelerator Center has recently been updated by the National Research Council of Canada with better photon and electron physics modules and christened EGSnrc. This code, originally developed for the purpose of investigating radiation safety in high-energy physics accelerators, can now be used at the MeV energies utilized in medical procedures and industrial radiation processes. Another code, PENELOPE, developed by at the University of Barcelona was also written with the electron and photon physics necessary to provide accuracy at fairly low energies. These codes, while quite advanced from the point of view of the underlying physics, can be difficult to apply to problems where the geometries are not simple. A similar code, the NIST code ETRAN, is also based on a simple geometry and contains a somewhat different electron-physics package. This package can be used in more complicated geometries through the Integrated Tiger Series of codes (ITS). This code series includes versions for slabs, cylinders and a combinatorial-geometry package. ETRAN, slightly modified, has also found its way into the Los Alamos codes MCNP and MCNPX (via ITS). The MCNP code includes the possibility of neutron transport; MCNPX also allows for the transport of heavier particles. Both of these codes have well-developed combinatorial-geometry packages. Other codes that are available (and their source) are COG (LLNL) and GEANT (Centre European de Recherche Nucleaire -- CERN). The former is similar in many ways to MCNP. The latter is a high-energy physics package finding increasing application in the MeV range. Clearly, it would take considerable expertise to be able to use all of these different codes, let alone develop and maintain them. In fact, most of these codes benefit from having a fair number of developers. As there are differences in the underlying physics, in databases and implementations, it is quite useful to be able to utilize more than one code in any given application in order to verify results.

With such a diversity of sources for physical data and for simulation codes, it is not surprising that there are a wide variety of applications that make critical use of these methods. Three recent applications addressed at NIST are noted. The first is the use of these codes to provide guidance to the United States Postal Service in their efforts to treat mail potentially tainted with anthrax. In addition to providing a computational model of an existing industrial facility and utilizing that model to reproduce

experimental measurements of dose, the models were then able to be applied to vary parameters not easily changed at the facility in order to determine a correct and efficient treatment procedure. (See Appendix B for more detail on the treatment of mail to eliminate biohazards.) A similar application for homeland security was a study of the possible treatment of high-risk passenger luggage in order to mitigate bioagents and pests. In this study, computational dosimetry was able to analyze configurations unavailable in current irradiation facilities. Finally, as an example of one of the many applications in the field of radiation-therapy field, NIST participated in a study of the dosimetry of beta-emitting brachytherapy sources. The short range of the emitted electrons makes measurement and calculation both quite challenging. In fact, this application represented a good test for code comparisons, aiding in the identification of coding and algorithmic problems. The medical community itself is finding evolving uses for these codes as exemplified in their use in developing three-dimensional (3D) dosimetry techniques (see MPD A.3.3). These codes are also useful in establishing dosimetry calibrations in the low-voltage electron beam area (see MDP D.8.0).

Clearly, a vital effort in using simulations in standards, homeland-security, industrial, radiation-protection and medical applications depends on the health of the underlying code-development efforts. These, in turn, need reliable atomic data. We present some actions and resources needed to keep these improvement efforts ongoing.

Action Items:

1 – Maintain and upgrade NIST databases for photon and electron interactions with atoms. Resolve outstanding issues regarding database incompatibilities among NIST databases and between NIST databases and current databases of external authorities.

2 – Maintain and upgrade NIST Monte Carlo tools. Determine if the Monte Carlo tools available to NIST are adequate for the national needs. Develop new Monte Carlo algorithms to address inadequacies.

3 – Develop computational models of calibration ranges and detectors.

4 – Develop computational understanding of standards-transfer process.

5 – Maintain ability to rapidly respond to urgent national needs in computational dosimetry.

6 – Promulgate and monitor the development of the use of codes by sustaining participation in groups such as the Radiation Process Simulation and Modeling User Group (RPSMUG).

Resource Requirements:

1 – In order to maintain current competency, a minimum of two person-years is now required.

2 – Additional personnel of at least one person-year are needed in order to initiate new developments.

Appendix A:
CIRMS Origin, Background and Operations

BUILDING A FORUM

THE START AND GROWTH OF THE COUNCIL ON IONIZING RADIATION MEASUREMENTS AND STANDARDS

Getting Started:

On January 8, 1991, Randy Caswell, then Chief of the Ionizing Radiation Division at the National Institute of Standards and Technology (NIST), invited a number of representatives from various academic and industrial associations and from different government agencies to attend a meeting at NIST on Tuesday, February 26, 1991. The purpose of this meeting was to discuss the formation of a new group that could bring to the Ionizing Radiation Division some "outside" perspective on the needs and longer-term goals involving almost all uses of ionizing radiation. This group would be patterned after the Council on Optical Radiation Measurements (CORM) that had been formed in 1972 to provide such guidance and commentary to the National Bureau of Standards (NBS), which subsequently became NIST, in the area of optical measurements and technology.

"Letters we have received and many discussions have pointed to the need for a committee to coordinate activities by NIST and others in the area of ionizing radiation measurements and standards."

Randy Caswell, Chief
NIST Ionizing Radiation Division
January 8, 1991

Of concern to those 27 attendees at this meeting was that the budgetary pressures of the time would shrink and diminish the effectiveness of federally funded coordinating committees and councils, such as the Committee on Interagency Radiation Research and Policy Coordination (CIRRPRC), chartered in April, 1984. This could leave a void in providing coherent direction to the scientific and technology efforts in ionizing radiation. Also of concern was how the now designated National Institute of Standards

and Technology would integrate its added congressionally mandated tasks of supporting the development of commerce and industry to these efforts.

The 16 organizations and associations present at this formation meeting all endorsed the concept of forming such a council, as did others who could not attend. Besides NIST personnel, this included representatives from DOD, FDA, the Federal Emergency Management Agency (FEMA) and NASA. The name of the council, the Council on Ionizing Radiation Measurements and Standards (CIRMS), was decided upon and a short list of possible functions was agreed upon. In addition, an Organizing Committee was formed to develop a structure for this new council and provide an initial slate of officers. This committee was composed of Randy Caswell as Chairman, Tom Heaton from the FDA, Bill Eckelman from NIH and Tony Berejka, from the industrial association, RadTech International North America.

Convening at a June 17, 1991, meeting, the Organizing Committee went about the business of developing DRAFT By-Laws, filing papers for incorporation in Maryland and applying for CIRMS 501c3 tax-exempt status from the IRS, with a substantial amount of detail being handled by NIST retiree, Elmer Eisenhower. A key point all had agreed upon was that the Council would be a distinct, privately funded entity, not dependent upon any specific allocation of government funding. A modest dues structure was developed, separating membership into three categories: corporate, organizational and individual.

In the development of the CIRMS By-Laws, an Executive Committee consisting of the President, a First Vice-President, a Second Vice-President, a Secretary-Treasurer, and a NIST representative were spelled out, with the Vice-Presidents succeeding each other and the President on a one year basis. As a matter of policy, the Organizing Committee felt that it would be best for the Council to rotate the elected officers from amongst the three main constituencies of the Council: industry, academia and government. A committee and subcommittee structure as it still stands was incorporated into the By-Laws.

By early 1992, the Organizing Committee had received acceptance from candidates for the elected offices in CIRMS and met at NIST on March 31, 1992, with these officers:

President Marshall Cleland, then with Radiation Dynamics, Edgewood, NY.
First Vice-President Peter Almond, University of Louisville, KY.
Second Vice-President Tom Bell, DOE in Germantown, MD.
Secretary-Treasurer Elmer Eisenhower, NIST retiree.

As the first CIRMS President, Marsh Cleland sent out letters of invitation on May 14, 1992, to various organizations, agencies and individuals to officially join CIRMS and to attend CIRMS first annual meeting, to be held at NIST on October 22 and 23, 1992. This inaugural day and one-half long meeting drew 63 participants and focused mainly on what CIRMS was and where it could be most effective. Following opening remarks by Katharine Gebbie, Director of the NIST Physics Laboratory, and Randy Caswell on "The Objectives of CIRMS," President Cleland chaired the opening day's major session. This was a panel presentation on "The Diversity of Ionizing Radiation Needs." Needs in 1) nuclear medicine, 2) radiation oncology, 3) diagnostic radiology, 4) industrial processing, 5) industrial radiography, 6) nuclear energy radioactivity, 7) nuclear power materials dosimetry, 8) defense, 9) radon, and 10) environmental radioactivity were addressed by a series of distinguished panel members. Bert Coursey followed this with a presentation on "The Commonality of Measurement and Standards Problems." As First Vice-President, Peter Almond then led an open discussion on "Bringing Diverse Uses and Common Interests Together." Elmer Eisenhower closed the day's activities by reviewing the CIRMS By-Laws. Tom Bell, as Second Vice-President, led the following morning's open discussion of the CIRMS committee structure and of what kind of tasks these committees could undertake.

By mid-February 1993, the chairmanships of the various committees had been sorted out. Bill Koch, a retired Chief of the NIST Radiation Physics Division and long-time Director of the American Institute of Physics, now at the University of Colorado, assumed the Chairmanship of the Science and Technology Committee. Tom Heaton, FDA, lead the Medical Subcommittee; Carl Gogolak, EML, the Public/Environmental Radiation Protection Subcommittee (PERP); Ken Swinth, then with Battelle Pacific Northwest Laboratory, the Occupational Radiation Protection Subcommittee (ORP); and Walt Chappas, then at the University of Maryland, the Radiation Effects Subcommittee. These were then and are still the designated subcommittees of the Science and Technology Committee as determined by the Committee Chair in consultation with the Executive Committee. Tony Berejka became Chairman of the Program Committee; Elmer Eisenhower Chair of the Finance Committee; Bill Casson, then at ORNL, Chair of the Communications Committee; and Second Vice-President Tom Bell, Chair of the Membership Committee. The NIST representative on the CIRMS Executive Committee was Randy Caswell (upon Randy's retirement in 1994 he was succeeded by Bert Coursey). With the initial officers in place and the Chairmanships of the Committees spelled out in the By-Laws filled, CIRMS became a functioning organization.

Building an Open Forum:

Annual Meetings: Following the initial meeting in 1992, annual meetings have been held every fall at NIST with the then President presiding over the meeting. Over the years these have evolved from topical presentations to focusing the major portion of the meeting on a single subject. As subcommittee participation has increased and the impact of the subcommittees became more noticeable, more time has been devoted to the subcommittees themselves reviewing and discussing their programs using a workshop format within the context of the meeting.

CIRMS Annual Meetings

Dates	Chair/President	Topic/Emphasis
October 22 and 23, 1992	Marshall Cleland	Formation meeting
November 8 to 10, 1993	Marshall Cleland	Medical Uses
November 16 to 18, 1994	Peter Almond	Measurement Quality (MQA)
November 28 to 30, 1995	Tom Bell	Advanced Techniques
November 12 to 14, 1996	Tony Berejka	Academic Contributions
November 12 to 14, 1997	Larry DeWerd	Secondary Laboratories
October 19 to 21, 1998	Bob Loesch	National Labs/Agencies
October 13 to 15, 1999	Tom Slowey	Subcommittee Activities
October 30 to November 1, 2000	George Xu	Advanced Radiation Measurements
October 29 to 31, 2001	Joe McDonald	Radiation Standards for Health & Safety
October 21 to 23, 2002	Art Heiss	Traceability and Standards
October 27 to 29, 2003	Geoff Ibbott	Radiation and Radioactivity Measurements and Standards in Industry
October 25 to 27, 2004	Jim Deye	Biological Dosimetry Measurements and Standards

Newsletter/Web Site: In the spring of 1994, CIRMS launched its own Newsletter. Under the editorial leadership of Bill Casson, the CIRMS Newsletter contained not only summaries of the organization's own efforts and activities, but also featured a broad range of topics of general interest to the entire ionizing radiation community. The CIRMS Newsletter has shifted format and news items are now incorporated and linked into on the CIRMS web site: www.cirms.org. This was inaugurated by Bill Casson and then supported by efforts from Past-Presidents Tom Slowey and Bob Loesch. Bob Loesch has taken on the responsibility of being the CIRMS "webmaster." Using this electronic media, more timely information can be conveyed to the CIRMS membership. Links are provided to CIRMS sponsors, related scientific and technical meetings and to each of the subcommittees of the Science and Technology Committee. CIRMS meeting summaries are also posted as well as links to papers given at CIRMS annual meetings.

Needs Report: During the CIRMS second annual meeting in 1993, the Science and Technology Committee agreed to prepare what was expected to be a series of regular reports on "National Needs in Ionizing Radiation Measurements." Bill Koch, the Chairman of the Science and Technology Committee worked with the chairmen of the four subcommittees who in turn developed 22 Measurement Program Descriptions (MPDs) in collaboration with their subcommittee membership. These subcommittee chairmen were:

Medical Subcommittee: Tom Heaton
Public/Environmental Radiation Protection: Carl Gogolak
Occupational Radiation Protection: Ken Swinth
Radiation Effects: Roger Clough

The process of developing a format as well as content took a number of months. After full review by the CIRMS Executive Committee, President Peter Almond, and concurrence with all subcommittee chairs, the first report on "National Needs in Ionizing Radiation Measurements" was published in January 1995. This report was widely distributed not only amongst NIST management and CIRMS membership, but also to key decision-makers in other federal agencies.

CIRMS decided to periodically review the progress on the programs described in this report and to produce such a report on a triennial basis. Joe McDonald succeeded Bill Koch as the Chairman of the Science and Technology Committee and thus assumed editorial responsibility for the second report on "National Needs in Ionizing Radiation Measurements and Standards" published in 1998. Progress was noted on various MPDs, some being completed, and new ones being added, with there being 23 MPDs in the new report. More extensive introductory sections were written and some pictures incorporated into the text to show equipment and facilities used in conducting the work

needed to meet the objectives described in these program descriptions. Each subcommittee prepared a roadmap for one of the MPDs in their section. The overall text increased from the 62 pages of the first report to 106 in the second. Again, the actual coordination in pulling together these MPDs was lead by the subcommittee chairs:

Medical Subcommittee: Tom Heaton
Public/Environmental Radiation Protection (PERP): Dave McCurdy
Occupational Radiation Protection (ORP): Ken Swinth
Industrial Applications and Material Effects (IAME): Paul Farrell

Following a similar CIRMS review process, this second "National Needs in Ionizing Radiation Measurements and Standards" was released by President Bob Loesch in time for the 1998 annual meeting. These first two "National Needs Reports" have been made available on the CIRMS web site.

The third "Needs Report" was released in October 2001 by President Joe McDonald. Past-President Tony Berejka was the editor, being the Chairman of the Science and Technology Committee. The roadmap concept was dropped in that for many MPDs the first action item was to obtain funding for the program described. It was also difficult to convey such roadmaps in concise graphics. A standardized format for all MPDs was introduced consisting of four sections: 1) the statement of the objective(s), 2) background information, 3) action items needed to meet the objective(s), and 4) resources, both in terms of personnel and equipment, required. Sixteen MPDs were included, reflecting the greater focus attained by reviewing the MPDs during the CIRMS annual meeting. The entire report was 110 pages, including introductory and appendix materials. Graphics were controlled so that the entire report could be easily transmitted over the Internet in a condensed format. The 2001 "Needs Report" was made available in both print and compact disk (CD) format. The subcommittee chairs again pulled together the needed input:

Medical Subcommittee: Tom Heaton and Larry DeWerd
Public/Environmental Radiation Protection (PERP): Dave McCurdy and Ken Inn
Occupational Radiation Protection (ORP): Ken Swinth
Industrial Applications and Material Effects (IAME): Roberto Uribe and Ken Koziol

The fourth "Needs Report" released in 2004 reflected several changes within CIRMS. The word "National" was dropped from the title since there is a growing international involvement in the radiation standards and measurements community. Three overseas national laboratories, the National Physical Laboratory (NPL) in the United Kingdom,

the Austrian Research Centre Seibersdorf (ARC), and the Physikalisch-Technische Bundesanstalt (PTB) in Germany, are organizational sponsors of CIRMS. In addition, representatives from other areas, such as Canada, Denmark (the Risø National Laboratory), and from the International Atomic Energy Agency have been participants in CIRMS meetings, often giving formal presentations. A realignment of the subcommittee structure was brought about by combining the PERP and ORP subcommittees into a single Radiation Protection subcommittee. The CIRMS interests in Homeland Security were included amongst the Radiation Protection MPDs. An independent Homeland Security subcommittee is in its formative stage. At previous CIRMS annual meetings, the critical role of computational methods in a variety of areas became more and more apparent. Thus a section on Computational Needs was developed. Tony Berejka again served as editor with the assistance of the chairpersons of the Science and Technology subcommittees and NIST personnel:

Medical Subcommittee: Larry DeWerd and Geoff Ibbott
Radiation Protection: Ken Swinth, Ken Inn and Carl Gogolak
Homeland Security: Mike Unterweger
Industrial Applications and Material Effects (IAME): Roberto Uribe and Ken Koziol
Computational: Steve Seltzer and Paul Bergstrom

This fourth "Needs Report" will be posted on the CIRMS web site and will only be available in CD format.

Workshops: CIRMS sponsorship or co-sponsorship of topical workshops has facilitated the implementation of many of the MPDs. These have been held at NIST or at other appropriate venues. The Medical subcommittee has worked in cooperation with the American Association of Physicists (AAPM). The PERP subcommittee had interacted with appropriate subcommittees within the ASTM International (ASTM) that deal with radioactivity measurements. The ORP subcommittee collaborated with the Health Physics Society (HPS). These interactions are maintained as well as those of the IAME subcommittee members with ASTM International subcommittees dealing with dosimetry. Such collaboration, as well as responsiveness on the part of NIST's Ionizing Radiation Division, has brought some MPDs to successful conclusion and enabled significant progress to be made on others.

Over the years, CIRMS has sponsored or co-sponsored over 40 workshops, averaging three or four per year. These workshops bring together a community of interest in a particular topic and begin to form the basis for new Measurement Program Descriptions (MPDs) – See Appendix C. The workshop format has been adopted as a

forum within the annual meeting with each subcommittee structuring its break-out session as more succinct workshops focusing on the general theme of the meeting.

Student Awards: In order to foster the development of young scientists and technologists in the various aspects of ionizing radiation, during 1999 CIRMS developed a Student Awards program, guided by then First Vice-President George Xu. Since then, CIRMS has awarded 23 Student Awards to cover the costs involved in attending the annual CIRMS meeting to graduate students from 13 different institutions. Each student presents a poster paper and gives a ten minute oral presentation covering his or her project. Summaries of these presentations are posted on the CIRMS web site. This program is an integral part of the annual meetings and flourishes with sustained sponsorship from some of CIRMS members, notably the Thermo-Electron Corporation, Amersham Health and NIST.

Year	Student	Institution	Area of Interest
1999	Ariel Drogin	University of Kentucky	Medical
	Jennifer Smilowitz	University of Wisconsin	Medical
	Oleg Povetko	Oregon State University	PERP
	Ahmet Bozkurt	Rensselaer Polytechnic Institute	ORP
	Kirt Marlow	Idaho State University	IAME
2000	Lesley Buckley	University of Wisconsin	Medical
	Peter Caracappa	Rensselaer Polytechnic Institute	Medical/ORP
	Scott Larsen	State University of New York	IAME
2001	Kurt Stump	University of Wisconsin	Medical
	Brigitte Reniers	Universite Catholique de Louvain	Medical
	Matt Buchholz	Oregon State University	PERP
	Michael Czayka	Kent State University	IAME
2002	Wes Culberson	University of Wisconsin	Medical
	Dickerson Moreno	University of Missouri	PERP/ORP
	Michael Shannon	Georgia Institute of Technology	PERP/ORP
	Ramazan Kizil	Penn State University	IAME
2003	Sheridan L. Griffin	University of Wisconsin	Medical
	Malcolm P. Heard	University of Texas	Medical
	Baodong Wang	Rensselaer Polytechnic Institute	PERP/ORP
	Shannon Helfinstine	Kent State University	IAME
2004	Jennifer R. Clark	University of Kentucky	Medical
	Stephen Davis	University of Wisconsin	Medical
	Carlos Roldan	University of Massachusetts Lowell	IAME

Distinguished Achievement Awards: At the annual meeting in 2002, "The Council on Ionizing Radiation Award For Distinguished Achievements in the Field of Ionizing Radiation Measurements and Standards" was initiated. Randy Caswell, the former Chief of the Ionizing Radiation Division at NIST and the person who help create CIRMS was given this award. Subsequently, the award was renamed in Randy's name. In 2004, H. Thompson Heaton, II, from the Center for Devices and Radiological Health, of the US FDA was the recipient. For many years, Tom had chaired or co-chair the CIRMS Medical Applications subcommittee and was instrumental in its success. In 2004, "The Council on Ionizing Radiation Measurements and Standards 2004 Randall S. Caswell Award For Distinguished Achievements in the Field of Ionizing Radiation Measurements and Standards" went to CIRMS Past-President and long time Chairman of the Science and Technology Committee, Tony Berejka.

Year	Caswell Award Winners
2000	Randall S. Caswell, NIST
2002	H. Thompson Heaton, II, US FDA
2004	Anthony J. Berejka, Ionicorp+

Organizing for Achievement:

Dialog: From its inception, CIRMS implemented several organizational procedures to assure that this new forum, that covers all aspects of ionizing radiation, would remain open and operate smoothly. Monthly conference calls amongst the members of the Executive Committee were immediately initiated. Now the chairs of the subcommittees of the Science and Technology Committee are invited to participate and guide the organization in its day-to-day activities.

Structure: At the second annual meeting that was held in 1993, Elmer Eisenhower accepted the role of Executive Secretary. His functions as Secretary-Treasurer were then taken over by Ken Inn who was elected by the membership to that post. Ken served in that capacity until the 1998 annual meeting when John Micka was elected Secretary-Treasurer. The functions of Secretary and Treasurer have now been split with Past-President Tom Slowey serving as Treasurer and Sandy Perle as Secretary. In mid-1995, Elmer Eisenhower expressed his desires to fully enjoy his retirement from NIST. The CIRMS Executive Committee thereupon began to search for a replacement. With good fortune, CIRMS found Katy Nardi and commenced to retain her as the Council's Executive Secretary. As CIRMS has grown, Katy has assumed more and more of the

administrative tasks in keeping the organization going. For example, she works closely with NIST's conference management personnel to assure that the annual meetings proceed without flaw.

As CIRMS has grown, the subcommittees of the Science and Technology Committee have found it beneficial to be co-chaired so that there is not that heavy a reliance on any one individual. The Medical Subcommittee is now co-chaired by Past-Presidents Larry DeWerd and Geoff Ibbott. The Public and Environmental Radiation Protection Subcommittee (PERP), formerly co-chaired by Dave McCurdy and Ken Inn, and the Occupational Radiation Protection (ORP), chaired by Ken Swinth, have been merged into one subcommittee, Radiation Protection, dealing with all facets in this area. For now, the interests in Homeland Security are expressed amongst those in the Radiation Protection area, whose subcommittee is now chaired by Ken Swinth, Ken Inn and Carl Gogolak. A distinct Homeland Security subcommittee is being formed under the Chairmanship of Mike Unterweger from NIST.

Executive Interaction: On September 11, 1995, CIRMS President Tom Bell held a meeting of the Executive Committee and subcommittee chairs at NIST to review the overall goals and objectives of the organization. By then, having several years of operational experience, CIRMS reformulated its Mission Statement and tightened the language of some of its original goals and objectives. These are now also posted on the CIRMS web site and are presented in the table below. Since then, every year the CIRMS Executive Committee convenes, prior to the annual meeting, to hold its annual retreat. With the chairs of the subcommittees of the Science and Technology committee present recent retreats have focused on the progress being made on the MPDs as spelled out in the "Needs Reports." Operational issues, such as the development of the web site, annual meeting program planning, and the like are also addressed.

Summary:

In a few brief years, the Council on Ionizing Radiation Measurements and Standards has constructed a unique open forum for dialog on all aspects of ionizing radiation. In the start of the new century, greater use of electronic communication and the Internet will be made. Each of CIRMS officers can now be addressed at the CIRMS web address, e.g, Katy@cirms.org will reach Katy Nardi, the Executive Secretary. However, the vitality and growth of any organization depends on its membership.

Appendix B:
The Effectiveness of CIRMS

B-1: RECOGNITION OF CIRMS VALUE BY NIST

January 21, 2004

Dr. James Deye
National Cancer Institute
6130 Executive Blvd., MSC 7440
Rockville, MD 20892-7440

Dear Dr. Deye:

I would like to congratulate you on yet another successful annual meeting of the Council on Ionizing Radiation Measurements and Standards (CIRMS), held recently here at the National Institute of Standards and Technology. The focus of this latest meeting, "Radiation/Radioactivity Measurements and Standards in Industry," clearly aligns with NIST's mission to "work with industry to develop and apply technology, measurements and standards." It is great to have so many representatives from the user community here on-site, and to hear their perspectives on the needs and developments in ionizing radiation research, measurements and standards in health care, homeland security, environmental and personnel protection, and industrial applications.

As an independent council that brings together experts involved in all aspects of ionizing radiation, CIRMS is a vital resource to our Ionizing Radiation Division and to NIST. The expertise within your organization, from government and national laboratories, the academic community and industry, provides us with valuable insight to help in our efforts to maintain the national standards in ionizing radiation and provide our services to our entire customer base. In particular, the CIRMS triennial report on "National Needs in Ionizing Radiation Measurements and Standards," along with its Measurement Program Descriptions, has proven invaluable in the strategic planning of the Ionizing Radiation Division. This report provides us with a consensus view of the needs in the field and allows the Division to efficiently leverage its resources with the customers' needs in mind.

I would like to commend CIRMS on its extensive efforts in promoting the highest quality of radiation and radioactivity measurements and standards. NIST and I endorse these efforts, and wish you the best success in CIRMS continuing activities.

Sincerely,

Arden L. Bement, Jr.
Director

B-2. IMPLEMENTATION OF A SUCCESSFUL MPD

MPD A.1: National Air-Kerma Standards for Mammography

Summary

In 1992, the US 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.

US Facilities, Staffing, and Funding

The appropriate US 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.

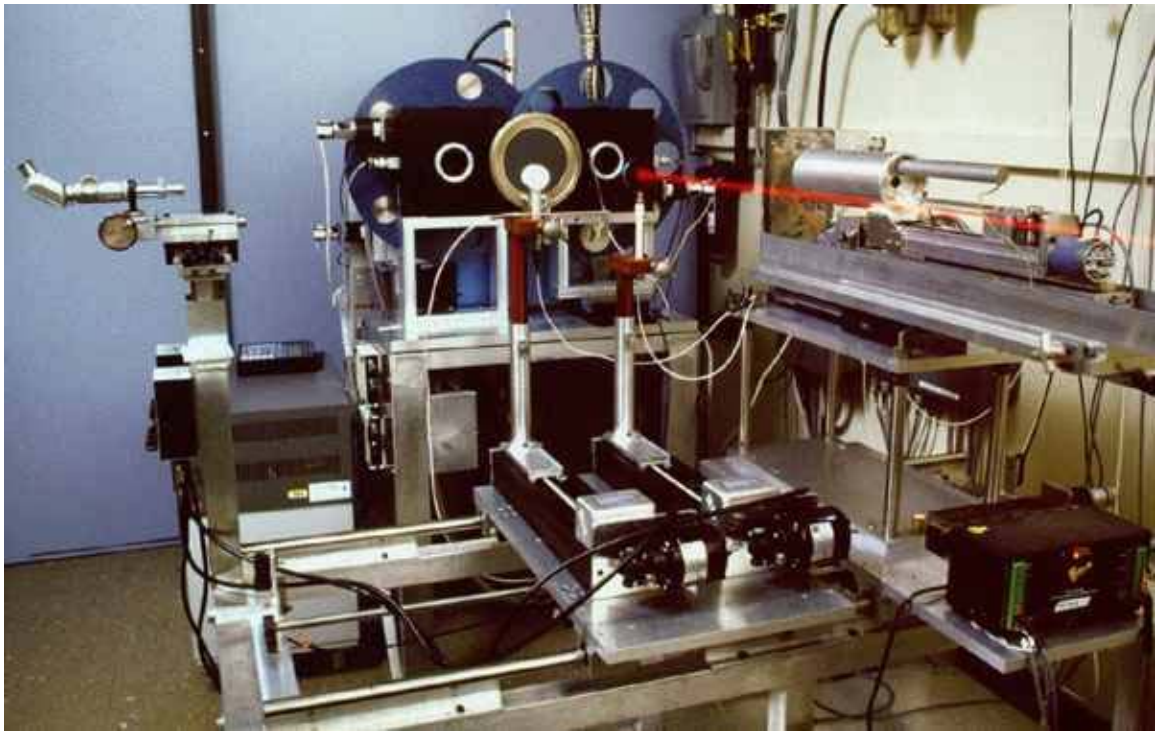

Figure A.1 – National standard calibration range for mammography testing

B-3. INVOLVEMENT OF CIRMS LEADERSHIP IN IRRADIATION SANITIZATION OF MAIL FOR THE US POSTAL SERVICE

Background: On October 15, 2001, a letter was opened in the office of then Senate Majority Leader Tom Daschle containing a white powdery substance. In it there was a hand printed note stating "We have this anthrax. You die now." This was postmarked October 9, 2001, from Trenton, New Jersey and processed through the Brentwood postal facility within the District of Columbia. Traces of anthrax were found in other Senate offices resulting from air-borne transmission of this potentially lethal fine powder. A comparable letter with the very refined white powder was found amongst mail addressed to Senator Patrick Leahy, postmarked the same day, from the same post office, processed through the same postal facility and containing a similar note.

As a result of the Daschle letter, numerous Senate personnel were tested for anthrax exposure and the Hart Senate Office Building was closed and quarantined. The use of the mail to transfer anthrax powder was tied into previous incidents of particulate anthrax exposure in Florida and New York, but of more coarse material. Five people died from the inhalation of anthrax, including three postal workers.

Since authorities did not yet know the scope or source of these anthrax transmittals, a pressing concern became the safety of the US mail itself. Radiation processing had long been known as a proven means for dealing with bio-contaminants in food and for the sterilization of medical devices. The US Postal Service (USPS) quickly sought to implement a means of assuring the safety of US mail via radiation processing.

National Academy of Sciences workshop: In response to a November 7, 2001, request from the House of Representatives Committee on Government Reform, the National Academy of Sciences assembled a panel of experts to review various options the US Postal Service had to "Ensure the Safety of the US Mail." This panel convened on November 14 at the National Academy and listened to and discussed various options, including considerations of the volume of mail handled by the postal service, the cost-effectiveness of various processes and the speed in which they could be implemented.

Serving on this eleven member panel were CIRMS Past-Presidents Marshall Cleland and Tony Berejka, then CIRMS NIST representative Bert Coursey and Mohamad Al-Sheikhly of the University of Maryland (subsequently to become a CIRMS Vice-President). A presentation on the effectiveness and possible through-put rates for electron beam processing was made by Yves Jongen from Ion Beam Applications (IBA).

Mail Irradiation: Bert Coursey was to lead an inter-agency Task Force under the President's Science Advisor to coordinate efforts amongst NIST, government agencies familiar with bio-hazards, as the FDA, the USDA and the Armed Forces Radiobiology Research Institute (AFRRI) and the US Postal Service (USPS). Preliminary irradiations were conducted at an 18 kW linac facility in Lima, Ohio and demonstrated the effectiveness of electron beam treatment in sanitizing the mail of anthrax. Dosimetry methods espoused by CIRMS for medical device sterilization were implemented by Marc Desrosiers and dose-distribution calculations made by Steve Seltzer from the Ionizing Radiation Division at NIST. It was found that mail could be effectively sanitized at 10 MeV using standard letter-carrying trays (Figure 1).

An alternate facility having a much higher powered 140 kW, 10 MeV electron beam, the IBA (now Sterigenics) facility in Bridgeport, New Jersey, was also found to have better suited logistics for handling the critical federal mail in specific zip codes within the District of Columbia. Mail irradiation has since transferred to this facility which can also do treatment of mail in bulk using its x-ray conversion capabilities (Figure 2 shows schematics of the electron beam and x-ray capabilities at this facility). This operation is still protecting certain mail from contamination using radiation processing.

Continuing Activities: The leadership of CIRMS continues to contribute to the ongoing federal efforts related to mail security. With a series of experiments informed by Monte Carlo calculations, an optimized mail irradiation process was developed that reduces the damage to potentially archive-able documents while maintaining a reasonable margin of safety. Having obtained White House approval, efforts are underway to see that this process is adopted by Congress and fully implemented. Further, it is anticipated that in 2006, the irradiation of federal mail will be performed in a federal facility in Washington, DC. CIRMS members are actively consulting with the US Postal Service and its contractors to insure adequate technical specifications before construction and process validation and before product release.

Follow-On Irradiation Efforts for Homeland Security: The USPS has donated two Titan 10 MeV, 18 kW, electron beam linacs and associated equipment to the NIST Ionizing Radiation Division. These are intended to be the basis for an irradiation processing test-bed facility that could help in the study of radiation mitigation of other threats, as well as for other industrial processes. At present, the Division lacks space suitable to house such a facility. If space within existing structures cannot be located,

then additional support will be required for new construction in order to move this project forward.

The success of the mail-irradiation efforts led to a project funded by the federal Technical Support Working Group (TSWG) to apply the Division's coupled experimental-computational approach to study the feasibility of the prophylactic irradiation of suspect passenger luggage to mitigate the introduction of agricultural diseases and pests into US agriculture. This study has shown that detailed Monte Carlo radiation-transport calculations are able to match accurate state-of-the-art experimental dosimetry to within about 10% to 15 %, allowing the use of computational dosimetry to explore the wide spectrum of possible geometrical complications and to accurately estimate requirements for possible airport-based facilities.

Figure 1. Dosimetry studies with mail in trays

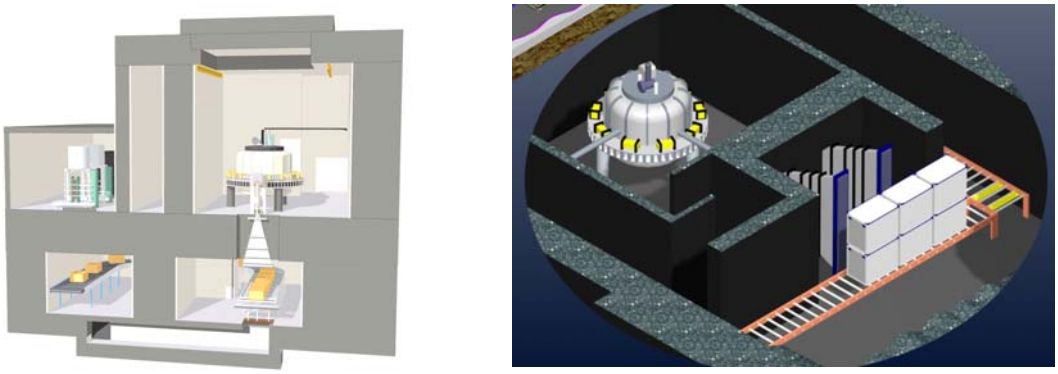

Figure 2. Schematics of IBA electron beam and x-ray irradiation processing facility

Reference: Cole, Leonard A**. The Anthrax Letters**, John Henry Press, Washington, DC (2003).

Appendix C:
CIRMS Workshops

Date	Topic	Subcommittee Interest
June 1994	Ocean Studies SRMs	PERP
March 1995	Radionuclide Speciation	PERP
March 1995	New NVLAP Criteria	ORP
September 1995	MQA for Gamma Processing	IAME
April 1996	Absolute Dose Measurements	Medical
April 1996	Mutual Accreditations	ORP
June 1996	Radiation Sterilization of Medical Devices	IAME
July 1996	Mid-year Workshop	PERP
July 1996	Mid-year Workshop	ORP
July 1996	Mutual Accreditations	Medical/ORP
September 1996	Therapeutic Radionuclides for Bone Pallation	Medical
February 1997	NIST Radiochemistry Intercomparison Program	PERP
March 1997	Iodine-125 Brachytherapy	Medical
October 1997	High Dose Electron Beams	IAME
October 1997	Electronic Personnel Dosimetry	ORP
March 1998	NIST Radiochemistry Intercomparison Program	PERP
April 1998	Measurements and Standards for Brachytherapy	Medical
September 1998	Radiation Protection Dosimetry	ORP
April 1999	Low-level Radionuclide Mass Spectometry and Atom-Counting	PERP

Date	Topic	Subcommittee Interest
April 1999	Measurements for Prostate Therapy Seeds	Medical
May 1999	μR-level Measurements and Standards	PERP
April 2000	Radiation Measurements in Support of Nuclear Material and International Security	General
April 2000	Computational Radiation Dosimetry	General
May 2000	Estimating Uncertainties for Radiochemical Analyses	PERP
October 2000	Dosimetry for Radiation Hardness Testing	IAME
October 2000	Measurements and Standards Infrastructure for Brachytherapy Sources	Medical
October 2000	Laboratory Accreditation for Personnel Dosimetry	ORP
October 2000	Drum Assay Intercomparison Program	PERP
October 2001	In-vivo Radiobioassay Phantoms	PERP/ORP
October 2001	Food Irradiation	IAME
October 2001	Intravascular Brachytherapy Sources	Medical
February 2002	Ultra-Sensitive Uranium Isotopic Composition Intercomparison Planning Meeting	PERP
September 2002	Electron Beam Treatment of Biohazards	IAME
October 2002	Traceability and Standards in the Medical Physics Community	Medical
October 2002	Traceability and Standards for Homeland Security	PERP/ORP
October 2002	Traceability and Standards in High-Dose Applications	IAME
April 2003	Advances in High Dose Dosimetry	IAME

Date	Topic	Subcommittee Interest
October 2003	Annual Meeting Focus: Radiation and Radioactivity Measurements and Standards in Industry	
	Subcommittee break-out sessions	Medical RP HS IAME
October 2004	DHS-EML/CIRMS REALnet (Radiological Emergency Analytical Laboratory Network) workshop	RP/HS
October 2004	Annual Meeting Focus: Biological Dosimetry Measurements and Standards	
	Subcommittee break-out sessions	Medical RP HS IAME

Appendix D:
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
AFRRI — Armed Forces Radiobiology Research Institute
ALARA—As Low As Reasonably Achievable
ANSI—American National Standards Institute
APL — Applied Physics Laboratory
ASTM—ASTM International
BAT — Biodosimetry Assessment Tool
BNCT — Boron Neutron Capture Therapy
BREL — Boeing Radiation Effects Laboratory
BRMD—Bureau of Radiation and Medical Devices
CAT — Computerized Axial Tomography
CDC — Center for Disease Control
CDRH—Center for Devices and Radiological Health
CERN—Centre European de Recherche Nucleaire
CI — Conformality Index
CIRMS—Council on Ionizing Radiation Measurements and Standards
CIRRPRC — Committee on Interagency Radiation Research and Policy Coordination
CORM — Council on Optical Radiation Measurements
CRCPD—Conference of Radiation Control Program Directors
CRT — Conformal Radiation Therapy
CT — Computed Tomography
DICOM — Diagnostic Image Formats
DHS — Department of Homeland Security

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

FDCPMC — Food, Drug, and Cosmetic Packaging Materials Committee

FEMA—Federal Emergency Management Agency

FSU — Florida State University

FTE—Full Time Employee

GIS — Geographic Information System

GMP — Good Manufacturing Practices

HS — Homeland Security

HPS—Health Physics Society

HPSSC—Health Physics Society Standards Committee

IAEA—International Atomic Energy Agency

IAME—Industrial Applications and Materials Effects

ICP-MS — Inductively Coupled Plasma - Mass Spectrometry

ICRP—International Commission on Radiological Protection

ICRU—International Commission on Radiation Units and Measurements

IEC—International Electrotechnical Commission

IMRT — Intensity-modulated Radiation Therapy

ISO—International Organization for Standardization

LANL—Los Alamos National Laboratory

LLNL—Lawrence Livermore National Laboratory

LS—Liquid Scintillation

MAP—Measurement Assurance Program

MAPEP— Mixed Analyte Performance Evaluation Program

MARLAP—Multi-Agency Radiochemistry Laboratory Analytical Procedures

MARSSIM — Multi-Agency Radiation Survey and Site Investigation Manual

MPD—Measurement Program Description

MQA—Measurement Quality Assurance

MQSA—Mammography Quality Standards Act

MRI—Magnetic Resonance Imaging

NASA—National Aeronautics and Space Administration

NBS — National Bureau of Standards

NCRP—National Council on Radiation Protection and Measurements

NDA—New Drug Applications

NIH — National Institutes of Health

NIRP — NIST Radiochemical Intercomparison Program

NIST—National Institute of Standards and Technology

NPL—National Physical Laboratory (UK)

NRC—Nuclear Regulatory Commission

NRC-Ottawa—National Research Council (Canada)

NRL — Naval Research Laboratory

NSWC—Naval Surface Weapons Center

NVLAP—National Voluntary Laboratory Accreditation Program

OCT — Optical Computerized Tomography

ORNL—Oak Ridge National Laboratory

ORP — Occupational Radiation Protection

OSL — Optically Stimulated Luminescence

PE—Performance Evaluation

PERP — Public and Environmental Radiation Protection

PET—Positron Emission Tomography

PMMA—Polymethyl Methacrylate

PNNL—Pacific Northwest National Laboratory

PTB—Physikalisch-Technische Bundesanstalt (Germany)

PWR—Pressurized Water Reactor

P2—Pollution Prevention

QA — Quality Assurance

REALnet — Radiological Emergency Analytical Laboratory Network

RESL—Radiological and Environmental Sciences Laboratory

RIMS—Resonance Ionization Mass Spectrometry

RMAP — Radiological Measurement Assurance Program

RP — Radiation Protection

RPSMUG — Radiation Processing Simulation and Modeling User Group

RPV—Reactor Pressure Vessel

RTP — Radiation Treatment Plan

SBIR — Small Business Innovative Research

SI — Systeme International

SPECT—Single Photon Emission Computed Tomography

SPI — Society of the Plastics Industry

SRM—Standard Reference Material

TIMS — Thermal Ionization Mass Spectrometer

TLD—Thermoluminescent Dosimeter

TRU—Transuranics

TSWG — Technical Support Working Group

USDA—United States Department of Agriculture

USPS — United States Postal Service

VOC — Volatile Organic Compounds

WHO — World Health Organization

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