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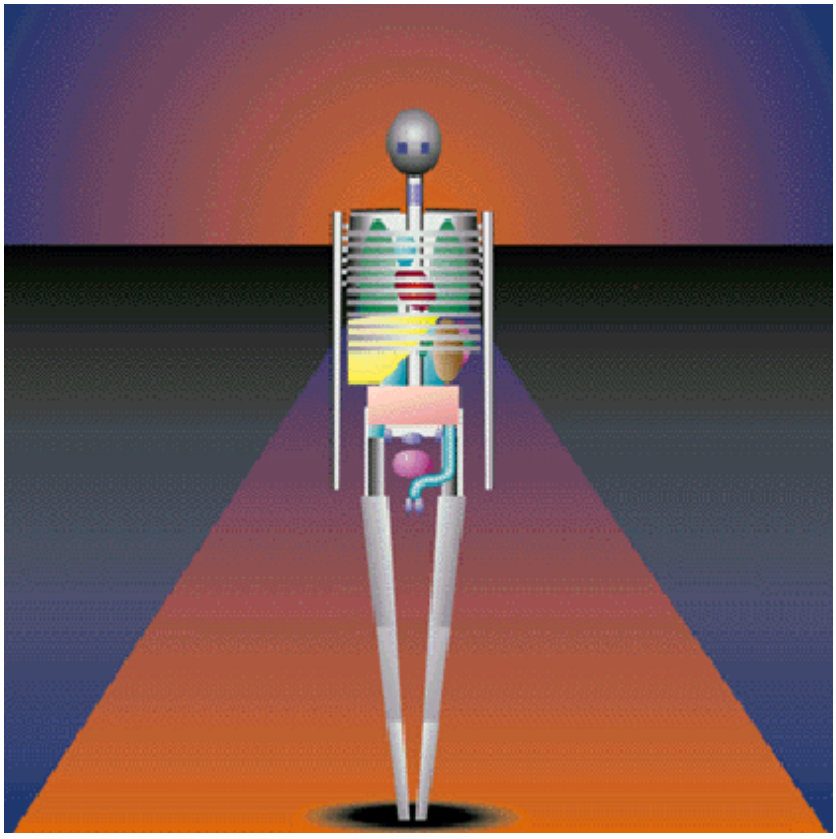
Council on Ionizing Radiation Measurements and Standards



Third Report on National Needs in Ionizing Radiation Measurements and Standards

Prepared by the CIRMS Science and Technology Committee

October 2001

The Council on Ionizing Radiation Measurements and Standards

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CIRMS Third Report on National Needs in Ionizing Radiation Measurements and Standards© 2001 – available from:

CIRMS
Post Office Box 1238
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$30 per printed copy; also available on disk at $20 per copy.

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Cover: Computer-generated image of simplified mathematical model of major human body structures and organs (courtesy of J.E. Tanner, Pacific Northwest National Laboratory).

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 third triennial report on "National 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 four 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 that deals with diagnostic and therapeutic uses of ionizing radiation has found need in three 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

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.

CIRMS Public and Environmental Radiation Protection Subcommittee (PERP) deals with radioactivity found in the environment and its possible public health effects. PERP has found need for Measurement Programs in three specific areas:

- Traceability to NIST for Reference, Monitoring and Service Laboratories
- Speciation of Radioactive Elements in Contaminated Soils and Sediments
- Atom-Counting Measurement Techniques for Environmental Monitoring

These reflect continuing needs to improve upon ways to measure radioactivity, especially in soils 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.

The CIRMS Occupational Radiation Protection subcommittee (ORP) deals with worker protection in radioactive environments. ORP has determined needs in six areas:

- Intercomparison Transfer Standards for Neutron Source Calibrations
- Improvements in *In-vivo* Radionuclide Metrology
- Improved Radiation Measurement Infrastructure for Occupational Radiation Protection
- Implementation of Electronic Dosimetry for Primary Dosimetry
- Extension of Calibration Accreditation Criteria to Low Dose Radiations
- Implementation of Support for Personnel Dosimetry Proficiency Testing per ANSI N13.11

Issues of calibration, proficiency testing and the maintenance of a network to monitor dose exposure in occupational settings are covered.

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 four areas:

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

Terrestrial measurements of the effects (hardening) of types of radiation found in space on electronic materials is 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 third triennial issuance of a "National 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.)

CIRMS brings these constituents together through workshops, its semi-annual newsletter and web site (www.cirms.org) and at its annual meetings. 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 then forth as Measurement Program Descriptions (MPDs).

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 broadened to include activities involving other national laboratories, to engage with non-US national laboratories, such as the National Physical Laboratory (NPL) in the United Kingdom, and to interact with a number of professional and industrial associations. Given the relatively flat funding for the NIST Ionizing Radiation Division over the past several years,[(1)] collaborative efforts are now essential to achieving the goals and completion of needed programs, the MPDs. In this regard, CIRMS has found outstanding cooperation within committees and subcommittees of other groups and organizations. For example, the agenda spelled out by the Science and Technology subcommittee on Medical Applications has benefited from interaction with the American Association of Physicists in Medicine (AAPM). The Health Physics Society (HPS) has had concomitant interests in the areas of concern to the Occupational Radiation Protection (ORP) subcommittee. The Public and Environmental Radiation Protection (PERP) subcommittee has interacted with activities involving the American National Standards Institute (ANSI) and the American Society for Testing and Materials (ASTM). The Industrial Applications and Materials Effects (IAME) subcommittee too relies on interaction with the relevant ASTM subcommittee.

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 (LANL), Oak Ridge (ORNL) and the Pacific Northwest laboratory (PNNL) also have members engaged in CIRMS activities. Most of these have all 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 Kent State University. The University of Notre Dame and Georgia Tech 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 few 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 third "National Needs Report," there are several key changes from the prior two editions ("Needs Report – I" of January 1985 and "Needs Report – II" of October 1998). 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. This third edition is more focused, targeting fewer MPDs and only 16 areas of interest. This does 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.

Given the budgetary constraints within NIST and in particular for the Ionizing Radiation Division, CIRMS now plays more of a role as a truly coordinating council, promoting interaction amongst diverse organizations in order to fulfill a national need. Because resource allocation and staffing are key to completing any program, CIRMS has

abandoned attempts to delineate "roadmaps" in favor of expressing activities needed to complete any program (any MPD) as a Action Items and then expressing Resource Requirements in terms of needed personnel and facilities. CIRMS is an independent expert advisory council, and not itself directly engaged in the allotment of resources.

Where CIRMS has been successful, it has indeed been able to draw together resources from different groups in order to focus talents on a specific need or issue. Appendix B presents the results of one such achievement, establishment of the "National Air-Kerma Standards for Mammography." This involved collaboration amongst NIST's Ionizing Radiation Division, the FDA Center for Devices and Radiological Health (CDRH), and the AAPM accredited dosimetry calibration laboratory at the University of Wisconsin.

CIRMS offers an excellent forum for academic and industrial cooperation on specific topics involving ionizing radiation, a sought after, but undeveloped, forum to promote sustained collaboration, for example, in the field of radiation chemistry.[2]

Within the context of each of the MPDs in this report, one will find a greater emphasis on collaboration amongst various organizations. The format for the Measurement Program Descriptions has been changed in order to more clearly state each program's objective, the measurement or standardization need, and to simplify the proposed route to meeting said objective. Where possible, pictures and charts are used to illustrate key items in each program area.

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.

References:

1. **An Assessment of the National Institute of Standards and Technology Measurement and Standards Laboratories – Fiscal Year 2000**; National Research Council; Washington, DC; pages 125 to 133.

2. **Research Needs and Opportunities in Radiation Chemistry Workshop**; Final Report of the workshop held April 19-22, 1998; U.S. Department of Energy, Office of Basic Energy Sciences, Division of Chemical Sciences; Germantown, MD.

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* US 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 in order to promote better and 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 a dynamic and on-target NEWSLETTER posted on 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.

- 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
- 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 semi-annual Newsletter
- CIRMS National Needs Reports
- CIRMS web page and interactive e-mail
- CIRMS electronic bulletin board
- News releases
- 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
- 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

MEASUREMENT PROGRAM DESCRIPTIONS

The national needs in ionizing radiation measurements and standards are presented in a consistent format called a "Measurement Program Description" or MPD. Each MPD has four basic components:

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

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

Action Items: Each MPD now lists specific tasks that are to 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, that 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 four groups, each the responsibility of one of the subcommittees of the Science and Technology Committee. For each grouping, there is an Introduction followed by the text of the MPDs themselves. A letter designation has been assigned to each subcommittee: A = Medical subcommittee; B = Public and Environmental Radiation Protection; C = Occupational Radiation Protection; and D = Industrial and Materials Radiation Effects. Within each group, the MPDs follow a sequential enumeration. On the first statement of an MPD it is assigned a number. Subsequent revisions are then noted with ascending decimal suffixes. Thus, MPD A.3.2 indicates a second revision of a MPD in the Medical area (the first revision having appeared in the 1998 second "National Needs Report"). Because of some confusion in the numbering of some PERP MPDs in the 1985 first "National Needs Report" and the second, new numbers have been assigned to the MPDs in this area.

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 Roentgen took an x-ray of a hand within a few days of the discovery of x-rays 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 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, e.g., 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, e.g., Technetium-99 (^{99m}Tc) is commonly used for many nuclear medicine procedures.

Historically the primary measurement laboratories, e.g. 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 chamber and extrapolation chambers have been used for the measurement of brachytherapy sources. The most recent application of these type of sources is intravascular brachytherapy for its use in studies of its role in preventing or inhibiting restenosis.

Recognizing that the only traceable units are Systeme International (SI) units and that in order to enhance patient safety to prevent errors, the Medical Subcommittee will only accept SI units. CIRMS is an organization dealing with measurement and standards, therefore 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). Curies is an old 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 Gy-m^2/s (Grays-m^2/s). The unit

U = μGy-m^2/h is recognized since it consists of SI units. Apparent activity is not a quantity as is activity; it is based upon the output of a source and only vaguely related to the contained activity since it is dependent on the source container.

DIAGNOSTIC RADIOLOGY

The national attention to health care and the goal of universal coverage have highlighted the need for cost effectiveness and quality assurance in the care provided to every U.S. resident. Breast cancer is the second leading cause of death by cancer in women. During their lifetime, one in nine women will develop breast cancer. The Center for Disease Control estimates that breast cancer mortality could be reduced by 30 percent if all women were screened regularly. The best way to prevent deaths from breast cancer is early detection. The best methods of early detection are self-examinations coupled with periodic mammograms. The goal of the Mammography Quality Standards Act (MQSA) was to provide high quality mammograms with the least radiation exposure. When MQSA was passed in 1992 there were no national standards for x-ray tubes commonly found in mammography units. The need for developing mammography air kerma standards was one of the four medical subcommittee MPDs in the first "National Needs Report" (1985). This MPD, the first to be completed, proved highly successful. As a result, national standards are now available for air kerma measurements from molybdenum and rhodium anode x-ray tubes. A network of secondary level laboratories is in place for calibrating the instruments that FDA inspectors use in their yearly inspection of mammography facilities, and for calibrating the instruments that medical physicists use in their yearly on-site evaluations of mammography facilities.

Most diagnostic x-ray exams are carried out at x-ray potentials between 80 and 120 kV and use filtration typical of the NIST moderately filtered (M) series of x-ray beams. Another MPD (A.5, see Appendix B) was completed so that NIST now offers M80 and M120 molybdenum beams as standard options.

THERAPEUTIC RADIOLOGY

One of the leading causes of death of Americans is cancer—over 25% of the population will die from some form of this disease. Ionizing radiation is one of the common treatment modalities, with over half of all cancer patients undergoing ionizing radiation treatment either for palliation or for cure (approximately 600,000 patients per year). The cost of these treatments is over $10 billion per year. The goal of radiation therapy is to kill the cancer while sparing normal tissue. This means using large doses of radiation

that must be accurately known and precisely delivered to the tumor. Radiation oncologists have been able to see clinically acceptable differences in the treatment of patients for variations as little as 5% in the delivered dose.

By far the most common types of radiation presently used to treat cancers are photons and electrons, although the use of brachytherapy sources is also common for treating some cancers such as prostrate 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 source of photons for brachytherapy treatments. The most recent application of brachytherapy sources is in intravascular brachytherapy for the prevention of restenosis. Other types of radiation used include protons, neutrons, and heavy ions. These latter radiations have features that make them desirable for treating some forms of cancer. For example, as protons are slowed down in tissue, they lose more of their energy per unit length just before they stop. Thus protons can be used to deliver more dose to the tumor and less to the surrounding tissue.

Historically the ion chambers used to measure the output of machines used for radiation therapy were calibrated free in air in terms of a exposure (or more recently air kerma) from a ^{60}Co unit and then using a protocol to convert the measurement to absorbed dose to tissue. A more straight forward approach 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 there was an MPD in the 1988 "National Needs Report" (A.4.1) for developing an absorbed dose to water standard based on a water calorimeter. A water calorimeter has been developed, which allows NIST to provide an absorbed dose to water calibration factor for ion chambers immersed in water phantoms.

The biggest new application of radiation in therapy is to investigate its role in preventing restenosis following balloon angioplasty. Approximately 40 to 50 percent of patients having angioplasty have a re-clogging of the arteries within six months. There are studies that show that doses of 10 to 30 Gy appear to be effective in preventing restenosis, although there are some issues that need to be resolved such as late thrombosis, geographic miss, "candy wrapper" effect, etc. In these studies radioactive sources are inserted into the artery through a catheter. These sources are in close proximity to the vessels so the determination of the dose at millimeter distances from the source is important. Methods to calibrate these sources at close distances are addressed in a revised MPD (A.7.1).

The need for high spatial resolution dosimetry in radiation therapy is important both for verifying the predicted dose distribution calculated using radiation therapy planning software particularly for multi-leaf, rotational arc treatments and for cases where one needs to know the dose distribution near brachytherapy sources. A revised MPD (A.3.2) identifies the needs for several of solid state systems capable of producing the required resolution.

With the development of improved methods of implanting brachytherapy sources in a precise manner for treating prostrate cancer, there has been a tremendous growth in the use of ^{125}I and ^{103}Pd seeds for this modality. The lack of air kerma strength standards for these brachytherapy sources as well as some problem with the Wide Angle Free Air Chamber (WAFAC) has caused some confusion in this application. A revised MPD (A.7.1) identifies the program needed to develop national standards for at least some brachytherapy source calibrations in terms of air kerma strength.

NUCLEAR MEDICINE

Nuclear medicine, the use of radioactively labeled pharmaceuticals in diagnostic and therapeutic applications, has undergone enormous growth since its introduction in the late 1940s. The needs for radioactive standards used in both diagnostic and therapeutic nuclear-medicine applications are the subject of the revised MPD A.2.2.

Diagnostic applications for *in-vivo* imaging have grown to 8.2 million procedures annually in the U.S. The chief reason for its continued growth is that radionuclides provide physiological information, as opposed to anatomical information (e.g., differences in tissue density) provided by the more common diagnostic x rays and magnetic resonance imaging (MRI). It has been estimated that over 80% of these diagnostic nuclear medicine procedures involve the use of six-hour half-life ^{99m}Tc. A score of other gamma-ray emitting radionuclides with half lives from a few minutes to a few days account for the other 20 percent. Some of the most prevalent procedures involve coronary imaging, tumor imaging, renal function studies, and skeletal imaging. Appropriate ^{99m}Tc-labeled radiopharmaceuticals have been developed for these and many other applications.

A second class of radionuclides used in diagnostic nuclear medicine is the short-lived positron emitters used for positron emission tomography (PET imaging). These include ^{11}C (20 minutes) and ^{18}F (2 hours), which are ideal because of the ease with which they can be incorporated into biomolecules. The use of PET is growing at a tremendous rate.

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.

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

A.2.2 Radioactivity Standards and Techniques for Nuclear Medicine

A.3.2 Dose Mapping Systems for 3D Conformal Radiation Therapy and Intensity Modulated Radiation Therapy

A.7.1 Absorbed Dose Standards for Brachytherapy Sources

MPD A.2.2: 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 for radiopharmaceuticals by the US Food and Drug Administration, 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. In the development of standards for radionuclides currently under development, there are many issues that need to be addressed. In many cases, level scheme or physical decay data (half-life, transition probabilities, etc.) may be suspect or require re-evaluation. In addition, new radionuclides on the horizon such as α-emitters present a number of technical challenges that must be overcome to develop standards for these radionuclides.

Standards and transfer standards must be developed early in the approval process to prevent discrepancies among trial sites, as well as discrepancies between theoretical and experimental dosimetry computations. One specific case in which a transfer standard solved such a dilemma is that of ^{188}Re liquid-filled balloons that are under investigation for use in preventing coronary restenosis after balloon angioplasty. An investigator observed a large discrepancy between the theoretical prediction of the dose rate from these devices and experimental dose rates obtained from calibrated radiochromic-film measurements. Through collaboration with NIST, it was a discovered that the dose calibrator setting for that radionuclide was in error by almost 25 %. By establishing a new calibration factor and providing a calibrated sample, NIST was able to assist the researcher in renormalizing the values for the activity contained in the balloons, which reconciled the theoretical and experimental dosimetry data.

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 (PET, 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, but requires new resources to meet the demands of an expanding nuclear medicine field and increasingly sophisticated technology requirements.

Traditionally, the Nuclear Medicine Standards Program at NIST has prioritized its activities on a more general agenda developed by direct interaction with the manufacturing and research communities. This gives the Program a general structure while enabling it to respond to the needs of these groups as they change. Nonetheless, a number of specific milestones have been established for activities covered under the following headings:

Therapeutic Radionuclides: Radiopharmaceutical manufacturers report that a number of ß-emitting nuclides, such as Lutecium-177 (^{177}Lu) and Holmium-166 (^{166}Ho), and ^{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. Therefore, studies are required that will characterize the changes in dose calibrator response to these variables.

There has been much interest lately in the use of alpha-emitting radionuclides such as Bismuth-212 (^{212}Bi), ^{213}Bi, and Astatine-211 (^{211}At) in radioimmunotherapy treatment for micrometastatic cancer, AML (acute myeloid leukemia), and other diseases which can be treated by targeting single cells. Early trial results at Memorial Sloan Kettering Cancer Center and Duke University are quite promising. The measurement challenges

posed by these radionuclides arise from the fact that the assays are now carried out over a decay chain of 2-4 daughters, all with different ß- and alpha-decay branching and also the fact that these radiopharmaceuticals are produced by either separating Uranium (U) or Thorium (Th) isotopes or by proton bombardment of a target in a cyclotron. These properties, along with the relatively close energies of emissions from neighboring nuclides, make impurity analysis difficult. There are additional chemical properties of these isotopes that present issues concerning source preparation and stability. All of these issues will need to be resolved before a standard of one of these nuclides can be produced.

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.

Another issue in quantitative imaging is the dissemination of NIST-traceable standards to the nuclear medicine community. Some of the properties of radionuclides used in diagnostic nuclear medicine, primarily the short half-life, tend to make distribution of a Standard Reference Material impractical except for a few sites that are located close to NIST. A possible solution to this may be the establishment of a program to calibrate users' re-entrant ionization chambers (dose calibrators) at NIST for specific radionuclides in specified geometries. Discussions will be required to establish the details of such a program, including the choice of radionuclides, geometries, and scheduling.

Brachytherapy: The use of implantable sources for the treatment of cancers such as that of the prostate continues to increase. Accurate radioactivity standards for the radionuclides currently being developed or already approved (^{103}Pd and ^{125}I) are required in order to normalize experimental dosimetry measurements, allowing them to be compared to theoretical models. Radioactivity assays of these sources could be performed by destructive or nondestructive means, such as has been done by NIST for a wide array of intravascular brachytherapy sources. However, accurate assays must rely on a standard for the radionuclide involved. The versatile radionuclide ^{125}I has been

standardized for over 25 years, but no such standard is currently available for the widely-used brachytherapy nuclide, ^{103}Pd. Palladium-103 decays primarily by electron capture to a state at 39.7 keV, which is followed by a highly converted E3 transition to the ground state. Thus, the dominant radiations that can be used for measurement are the x-rays, Auger electrons, and conversion electrons. Possible techniques that can be employed for these measurements include calorimetry and liquid scintillation counting.

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. Specific milestones in this category are difficult to define, due to the fact that the nature of many of these factors cannot be predicted beforehand. Nonetheless, this is an important part of standards development and must be included as part of any Measurement Program.

Present Status: NIST can provide activity measurements to better than 1% and can provide impurity analyses. Facilities are also available for physical decay property measurements. The program continues to be very active. However, expansion in terms of equipment, laboratory space, and manpower is needed to keep pace with the demands of a rapidly growing industry. Intercomparisons amongst the various National Metrology Laboratories (NIST, PTB, LPRI, NPL, etc.) are an important tool in developing internationally consistent measurement capabilities

Manufacturers such as Nycomed Amersham, Du Pont, Mallinckrodt, and many others have systems in place to accurately assay the bulk radionuclides, and they can demonstrate traceability to NIST by intercomparisons through the NIST/NEI radiopharmaceutical Measurement Assurance Program. This program will distribute standard reference materials for ^{89}Sr, ^{90}Y, ^{125}I, and others as determined by the industry. Wider participation in the program by major commercial radiopharmacies, instrument manufacturers and hospitals can provide better measurement quality assurance at all levels.

If the nuclide emits gamma-rays, it must be assayed prior to administration in a calibrated dose calibrator. Good Measurement Practice should include on-site assays of all radiopharmaceuticals, although the pharmacy will most likely rely on the

manufacturer's assay for alpha- and beta-emitters. However, liquid scintillation, use of calibrated re-entrant ionization chambers, or similar methods, if available, should also be used as a confirmation.

Action Items:

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

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

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

4 – Develop primary standard for ^{103}Pd.

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

6 – Conduct workshops and seminars to bring together diverse organizations needed to accomplish the desired goals, including participation from universities, government agencies, e.g. 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.3.2: 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 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 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 CT and 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 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.

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 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.
- 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 etc…
- Export the final report in a standardized format that enables interactive evaluation by medical physicists.

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 minimum of 5 person-years 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.

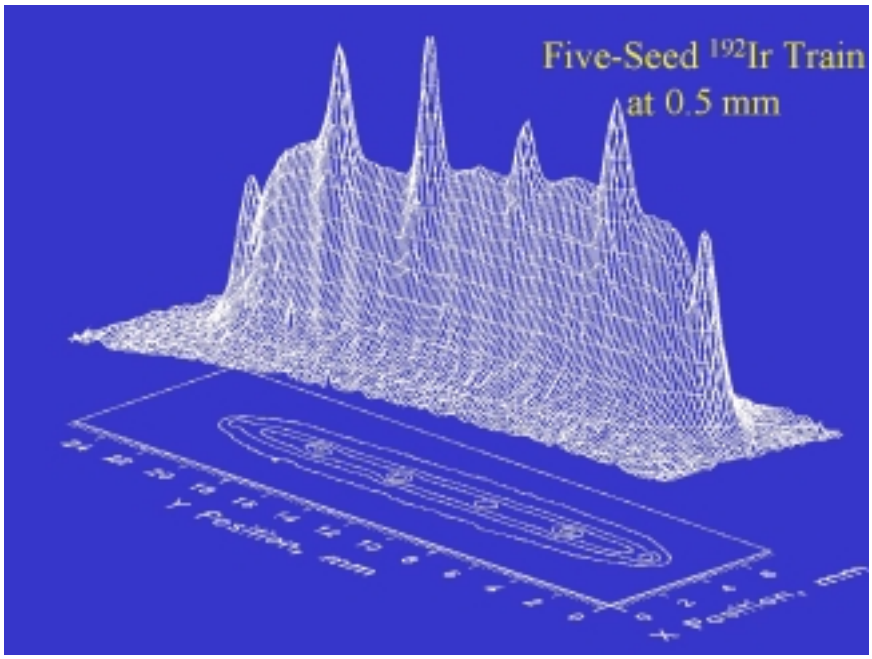

Figure A.3.2 – Autoradiograph of a series of iridium-192 seeds taken with a radiochromic film dosimeter.

MPD A.7.1: 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 3 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 a 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 measure source anisotropy directly.

With the increasing acceptance of implants as a leading method of treating conditions which are quite common, the manufacturers are responding by creating new source designs to compete for a part of the large market. Direct measurements offer the advantage of increased accuracy and shorter validation times for clinical applications.

NIST currently only offers calibrations for ^{125}I brachytherapy sources in terms of air-kerma strength. NIST has been engaged in a Cooperative Research And Development Agreement (CRADA) with Photoelectron Corporation to investigate the use of a 3 dimensional polar-coordinate water phantom for use in characterizing brachytherapy sources. This water phantom was developed for use with the company's miniature X-ray generator. The principles of its operation are suitable for characterizing brachytherapy sources. The water phantom moves a detector (ionization chamber presently, or fiber optic scintillator, for example) in spherical coordinates about the source. This is automated and can run unattended for hours at a time if necessary. The long term goal of MPD A.6 is the development of an absorbed dose rate standard for photon brachytherapy sources. This MPD is in effect accomplishes that goal. The technique is generally applicable to beta sources as well, if the detector is suitable. The water phantom at NIST is equipped with interchangeable detector housings. Presently, two ionization chambers and the PTW Optidos fiber optic scintillator probe are accommodated. Other detectors can be mounted which might be more suitable for different sources. Photoelectron commissioned PTW to build a very small volume parallel-plate ionization chamber for this water phantom. This chamber can be calibrated in the NIST standard beams for use in the water phantom. The small size of

this chamber improves the spatial resolution of the system. One goal will be to select and characterize detectors for different brachytherapy sources:

Sources: ^{125}I, ^{102}Pd, ^{192}Ir, ^{32}P, and a miniature x-ray source.

Detectors: ionization chambers, plastic scintillators, and diamond detectors.

Standards need to be established at NIST that can then be transferred to the medical physics community. The water phantom system is currently sold as an accessory for the miniature X-ray source. It is available to the ADCLs and the end users of brachytherapy sources. Adaptations to the software and detector housing might be required to optimize it for radioactive sources. The water phantom is presently on loan from Photoelectron to NIST for the duration of the CRADA. Photoelectron will supply support for mounting new detectors and assisting with mounting sources.

Action Items:

1 – Using three different detector systems, 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 the CRADA.

Resource Requirements:

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

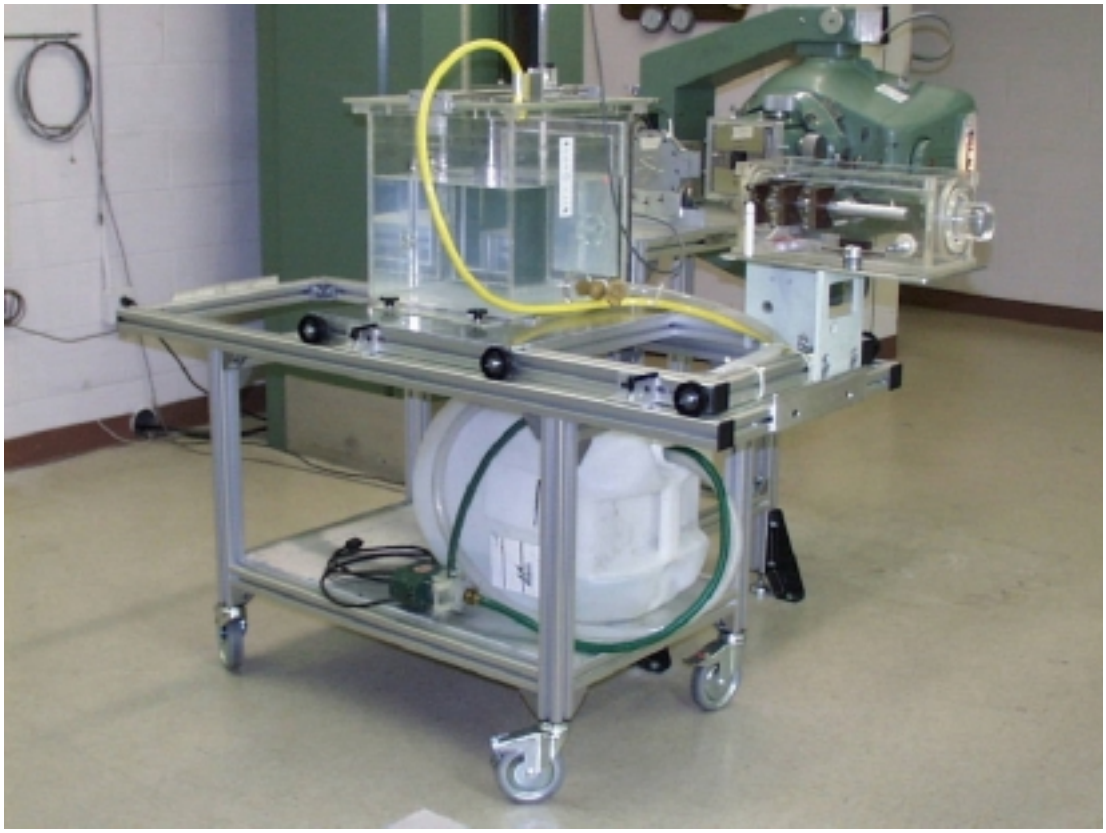

Figure A.7.1a -- Water phantom set up for absorbed dose to water measurements. (Courtesy of K&S Associates)

Figure A.7.1b – Radioactive seeds used in prostate cancer therapy.

B. PUBLIC AND ENVIRONMENTAL RADIATION PROTECTION MPDS

INTRODUCTION TO 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 (TRW) in temporary storage,

- Hundreds of thousands cubic meters of high-level waste in temporary storage, and

- Millions of cubic meters of low-level waste in temporary storage.

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

As the various government agencies better define their interactive roles in the environmental remediation and compliance activities, there has been a growing need to define programs that have multiagency consensus so that the remediation activities performed by one agency will be accepted by the other participating agencies. After several years of development, the DOE, EPA, NRC and DOD have prepared a document entitled "Multi-Agency Radiation Survey and Site Investigation Manual"(MARSIM) 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, DOC and DOI for

radioanalytical services (Multi-Agency Radiation Laboratory Protocols Manual - MARLAP) related to plant decommissioning and site remediation activities is in its final stages of review before publication. 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- & 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 histopathology, 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. 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 and synthetic urine, feces and body organs. 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, 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.

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. In conformance with ANSI N42.23, DOE initiated (1999) the Radiological Traceability Program as a means to establish traceability to the national standard for its formal laboratory performance evaluation programs for contract radioanalytical services.

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

B.7 Traceability to NIST for Reference, Monitoring and Service Laboratories

B.8 Speciation of Radioactive Elements in Contaminated Soils and Sediments

B.9: Atom-Counting Measurement Techniques for Environmental Monitoring

MPD B.7: TRACEABILITY TO NIST FOR REFERENCE, MONITORING AND SERVICE LABORATORIES

Objectives: Develop a National Measurement Assurance Program for the Radioanalytical Community Consistent with ANSI N42.23 and Traceable to NIST

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

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

Currently, there are two principal government national measurement programs related to environmental sample radioassay laboratories. These include the U.S. Environmental Protection Agency's PE PROVIDER Program administered by the National Voluntary Laboratory Accreditation Program at NIST, and the Department of Energy's Quality Assurance Program administered by the Environmental Measurement Laboratory, New

York, NY. Other government MQA programs include those for in vitro and in vivo bioassay as well for the mixed analytes in a waste matrix (MAPEP) administered by DOE's Radiological and Environmental Sciences Laboratory (RESL). In addition, RESL provides a nuclear power plant effluent MAP service under contract to the US Nuclear Regulatory Commission. Recently, there has been a number of DOE specific measurement assurance programs (MAPs) established in support of the Sample Management Offices at the various DOE sites for the analytical data verification and validation process. Of the many long-term and recently created government and commercial MAPs, currently only the DOE/EM's Radiological Traceability Program (RTP) Administered by the DOE National Analytical Management Program have measurement traceability to NIST. Traceability criteria for this program were established between the DOE and NIST in the 1997.

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

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

This MPD was recognized as a major priority in November of 1996. Since the 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 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. Two national programs have been implemented since 1997: the "NIST Radiochemistry Intercomparison Program" or NRIP and the Radiological Traceability Program (RTP) of the Department of Energy's Environmental Management. The Radiological and Environmental Sciences Laboratory and the Environmental Measurement Laboratory have been designated as DOE reference laboratories under the RTP. The RTP provides the performance evaluation program for the reference and monitoring laboratories for the DOE complex using the ANSI N42.23 framework. Although the RTP has completed its second year of a four-year sample exchange program with NIST, it continues to undergo program development as the program mature. NRIP provides NIST traceability to those laboratories participating in the quarterly exchange of environmental and radiobioassay performance testing samples provided by NIST. Funding of the RTP and NRIP have been secured for FY2001.

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 – RTP and NRIP should establish steering committees comprised of NIST and government and commercial laboratory stakeholders. These steering committees should focus on:

a) Recommending the program elements of a national MAP and the working relationship between NIST, reference, monitoring and service laboratories and the administrating agency.

b) Developing a "needs" MAP sample matrix in terms of radionuclides, media type and analyte concentration level.

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

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

e) Establishing 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 mechanism to facilitate the equitable funding of a national MAP involving government and private testing laboratories.

Resource Requirements:

1 – For each program (RTP and NRIP), one FTE or contractor equivalent at NIST for program administration, development of the necessary technical capability and the preparation and analysis of the test samples of the programs. The scientist 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.

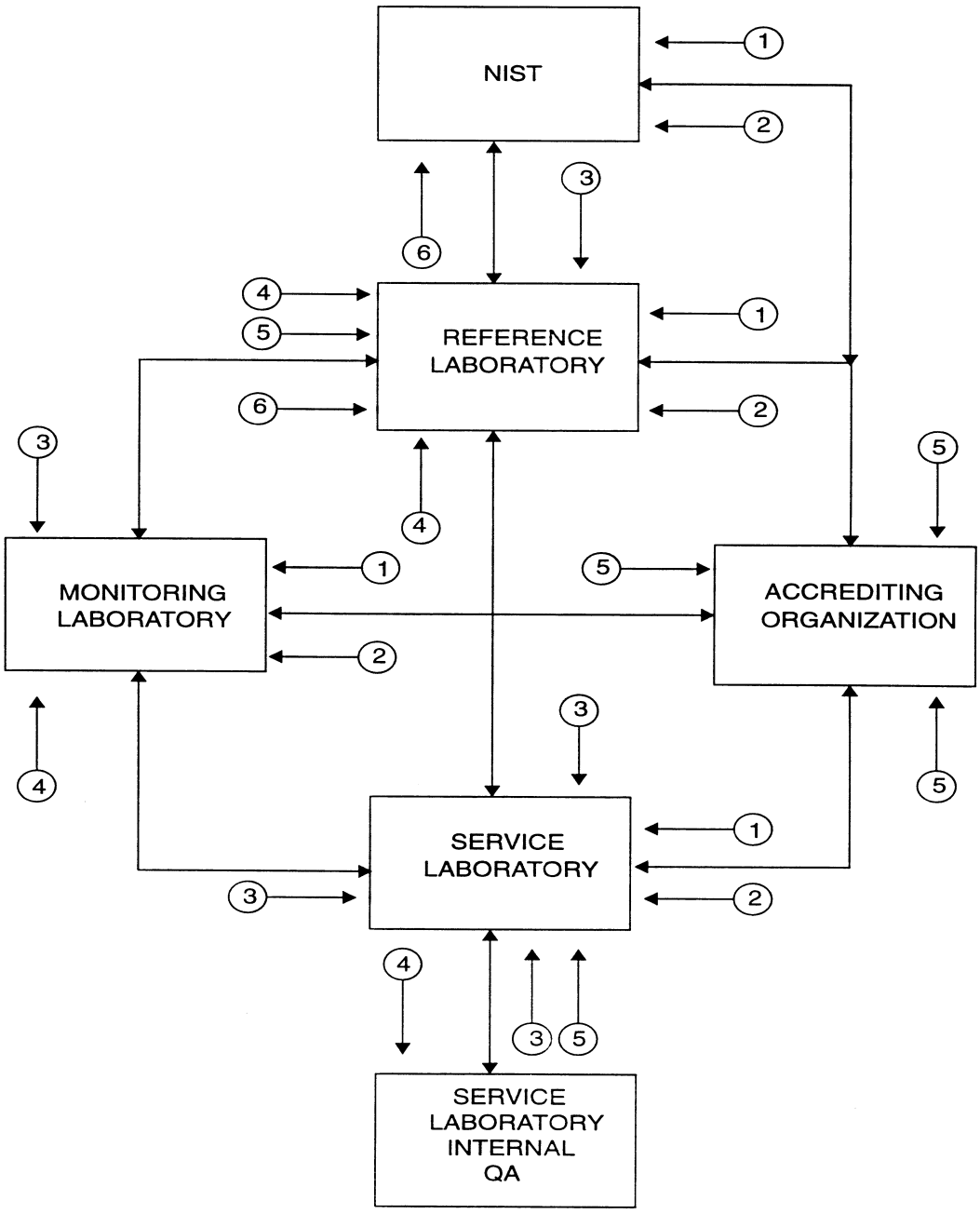

Figure B.7 – Diagram of national performance testing program per ANSI N42.23.

MPD B.8: SPECIATION OF RADIOACTIVE ELEMENTS IN CONTAMINATED SOILS AND SEDIMENTS

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

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

Background: Extensive areas of soils and sediments within Department of Energy sites have been documented as having significant radioactive contamination. Within current budgetary constraints, there are far more radiologically-contaminated sites at former nuclear weapons facilities than 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 availability" of the relevant contaminating species is a critical issue. There is a more pressing need to remediate sites where radioactive ions may be in more mobile forms than sites where the contaminants are known to be firmly fixed in the soil matrix. Recent studies have shown that the speciation of contaminating elements plays a very important role in dictating whether an ion may move into the food chain. How then does one measure environmental availability?

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 availability or potential mobility of that element in the environment. In other words, one commonly interprets a species as "mobile" or "labile" if it is present in one of the early, less harsh, treatments in a typical sequential extraction series. 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 soil samples.

The sequential extraction approach is appealing because: (1) the analytical protocols are relatively rapid and simple; and (2) the cost is reasonable. Unfortunately, there is considerable controversy 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 soils and sediments. The use of sequential extractions to characterize the nature of radiological contamination in soil 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 intercomparisons 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 MS 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 intercomparisons 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.

Resource Requirements:

1 – One NIST contractor is 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 – One full time employee (FTE) at NIST to coordinate and conduct the certification of the new line of natural-matrix environmental SRMs for extraction of radionuclides. Estimated cost of $200,000 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 2 laboratories) over a period of 3 years. In the second stages of the investigation, several expert personnel and facilities would be brought into the project in an interlaboratory comparison to evaluate the efficacy and reproducibility of the recommended protocol in different laboratories. The third phase would consist of the certification of benchmark radioactivity reference materials for community use.

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.

Figure B.8 – Soil sampling for radioactive contamination.

MPD B.9: ATOM-COUNTING MEASUREMENT TECHNIQUES FOR ENVIRONMENTAL MONITORING

Objective: Develop the capability and resources to provide NIST traceable reference materials and 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 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. Thus, a need exists for reducing the cost of these programs by developing techniques that: (1) use atom-counting to reduce time spent by factors of 10 per assay, and (2) perform measurements in situ if possible, thus avoiding laboratory analyses.

In addition to environmental sample analyses for the long-lived nuclides, current studies have shown that atom-counting is very applicable for radiobioassay for certain radionuclides. 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), the Lawrence Livermore National Laboratory (LLNL) and the Battelle National Laboratory. The application of atom-counting to bioassay will produce cost savings and will enable health physicist to document internal uptakes orders of magnitude better than current levels.

New atom-counting, neutron interrogation, and radiochemical techniques including calorimetry and a pulse recording instrument for coincidence measurements will be developed. These will provide new technology and reference materials for the assay of environmental radioactivity. NIST has recently conducted a Cesium-137 (^{137}Cs) "proof-of-principle" experiment using Resonance Ionization Mass Spectrometry (RIMS). 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, that has sensitivities in the part-per-trillion range, or better. This requires development of a source that can generate neutral atoms with appropriate constant wave beam intensity, width, and other characteristics.

The potential impact is enormous. A proposed 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 Pu, Technetium-99 (^{99}Tc) and Iodine-129 (^{129}I) were discussed. ASTM standard C1310-95 for the application of ICP-MS for ^{99}Tc, Thorium-230 (^{230Th}) 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 ^{235,238}U in urine to support radiobioassay programs is currently in the ASTM balloting process.

Other recently published ICP-MS methods include those for

- Radon-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.
- ^{99}Tc in urine bioassay developed at the Oak Ridge National Laboratory.
- Uranium isotopic abundances in groundwater and drinking water developed by Department of Energy—Methods Compendium.

Several national laboratories are using mass spectrometric techniques to evaluate ^{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 ICP-MS 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 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.

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 U.S. 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 the second intercomparison study to evaluate the capability of various mass spectrometric techniques for the assay of ^{239}Pu 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 mass spectrometry 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 shape 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 analytical capabilities at NIST.

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

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.

C. OCCUPATIONAL RADIATION PROTECTION MPDS

INTRODUCTION TO 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 is 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 U.S. 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.

ACTIVE MEASUREMENT PROGRAM DESCRIPTIONS

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

C.3.2 Intercomparison Transfer Standards for Neutron Source Calibrations

C.4.2 Improvements in *In-vivo* Radionuclide Metrology

C.17.1 Improved Radiation Measurement Infrastructure for Occupational Radiation Protection

C.18.1 Implementation of Electronic Dosimetry for Primary Dosimetry

C.19 Extension of Calibration Accreditation Criteria to Low Dose Rate Radiations

C.20 Implementation of Support for Personnel Dosimetry Proficiency Testing per ANSI N13.11

MPD C.3.2: 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 TLD system as transfer standards in intercomparison measurements and for proficiency testing of calibration laboratories seeking accreditation by NVLAP for dosimetry. When the irradiation conditions have been established the study needs to be extended to additional U.S. 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 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 U.S. 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-U.S. 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.4.2: IMPROVEMENTS IN IN-VIVO RADIONUCLIDE 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 radiobioassay (whole-body and organ counting) 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 80% differences 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 radiobioassay. This is a recommendation of the International Workshop on Standard Phantoms for In-Vivo Radioactivity Measurements [**Health Physics**, **61**, 893 (1991)].

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

Substantial progress has been made on this measurement program over the past few years. Standards working groups have been established through the HPSSC (HPS standards committee), work has been performed on materials development, modeling 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. The use of the ANSI N13.30 Standard Performance Testing for Bioassay Laboratories has been adopted by USDOE, and incorporated into the DOE Laboratory Accreditation Program. DOELAP has been performing accreditations of US National Laboratories since 1998. The standard has been the basis for the development of an international standard by ISO. Future progress is expected on the completion of the calibration phantom standards, dose calculation standards and the continuation of accreditation programs.

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

MPD C.17.1: 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 U.S. interests.

Accreditation: Accreditation provides a method of ensuring that calibrations, dosimeter processing or test measurements are performed in a quality manner consistent with established standards or criteria thus providing assurance that the results are consistent with national needs. In addition it is necessary to ensure that the accreditation programs are consistent, cost effective, and appropriate in terms of national and international needs. There are presently four national programs that accredit secondary calibration laboratories in the area of ionizing radiation dosimetry in the protection range. Although the critical elements of a complete measurement quality assurance (MQA) program are required for accreditation under each of these programs, they do not use the same general or specific criteria to evaluate candidate laboratories. The criteria are similar, but not identical. Questions have been raised about the comparability (equivalence) of accreditation granted by the various programs. An obvious major improvement would be the adoption, by all the programs, of 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. Now 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 IEC is working on a standard for evaluating the uncertainty of measurements made with instruments. These standards consider a greater range of influence quantities than the NVLAP and DOELAP standards and provide a rational basis for evaluating dosimetry against guidance by the ICRP.

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 U.S. practice and U.S. regulations. In general this is a continuing effort involving a moderate amount of time from a large number of individuals. In terms of identifying new standards, 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.18.1: IMPLEMENTATION OF ELECTRONIC DOSIMETRY FOR PRIMARY DOSIMETRY

Objective: Evaluate the reliability of electronic dosimeters and provide guidance for their use in monitoring worker exposure dosage.

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

CIRMS has acted as a forum for the electronic dosimeter and has assisted the manufacturers in establishing a group to consider and recommend type testing criteria for the electronic dosimeter. However, the electronic dosimeter does not fit well with the current standards and accreditation schemes as formulated. The ED and other new dosimeters may require changes in the present accreditation schemes and may require formal type testing. Tracking of the limitations in the ED and reviewing the requirements for the support infrastructure (beyond the formal performance testing issues) are also needed. Core standards for the type testing and the proficiency testing of the dosimeters have been identified. Guidance is needed on the implementation of programs. Mechanisms to identify limitations and progress made in eliminating the limitations (deficiency reports, technical reports, vendor performance, product improvements, etc.). Mechanisms to ensure that the ED is producing data that are as good as and reliable as that obtained from existing dosimetry systems.

Action Items:

1 – Identify standards that support the radiation measurement infrastructure needed for the protection of occupational workers using electronic dosimetry.

2 – Identify the operational elements (e.g. deficiency reports, technical reports, vendor performance reports, product improvements, etc.) that are needed to ensure that electronic dosimetry is used appropriately and to ensure the continuing reliability of the electronic dosimeters.

3 – Identify the appropriate interfaces with international dosimetry database groups and establish of the appropriate interfaces where needed.

4 – Assist users in the integration of electronic dosimetry into their active programs meeting both dosimetry and legal requirements.

5 – Conduct periodic workshops to monitor the progress and implementation of electronic dosimetry.

Resource Requirements:

1 – Funding to facilitate the needed workshops and action items is estimated to be <$50,000. Such workshops need not be conducted on an annual basis.

Figure C.18.1 – Electronic personnel dosimeter calibration.

MPD C.19: EXTENSION OF CALIBRATION ACCREDITATION CRITERIA TO LOW DOSE RATE RADIATIONS

Objective: Promote the development of calibration accreditation programs for low dose rate calibrations

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

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

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 CRCPD, NIST and DOE. Currently the traceability of such low-level measurements to national physical standards and the implementation infrastructure (accreditation) are not available. 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. At present, NIST does not provide direct calibration measurements at such low levels, but it is possible to extend capability to these lower levels and provide assurance that the fields are reasonably characterized through the accreditation process. It may be possible to remain within the 7% uncertainty established in our criteria for levels from 0.5 to 100 mR/h. However, since the NIST will not be able to provide direct proficiency tests it will require some rewording of the accreditation criteria. Extension of "traceability" to radiation types and intensities not directly served by the NIST is a topic that has been considered by CIRMS and is expected to be the topic of a position paper. K & S Associates are working on establishing such fields for calibrations and on the required procedures. It is expected that K &S will propose that the HPS become involved in such accreditation activities. During the accreditation renewal process, the assessment committee will review the K & S procedures and physical layouts for low-level calibrations.

Action Items:

1 – Develop draft criteria for extension of accredited calibrations to low dose rates.

2 – Develop methodology for proficiency tests for low dose rates collaborating with non-U.S. standards laboratories relying upon extension from known dose rates.

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

4 – Achieve accreditation for secondary calibration laboratories.

Resource Requirements:

1 – 1/4 person-year per year over the next three-year time frame is required to develop and implement criteria for low dose rate calibrations through existing accreditation groups as the Health Physics Society or Conference of Radiation Program Directors.

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

3 – An additional 1/4 person-year per year will be needed to investigate the extension of present dose rate calibration capabilities to low dose rates and determine if such a service is available through non-U.S. national laboratories.

MPD C.20: IMPLEMENTATION OF SUPPORT FOR PERSONNEL DOSIMETRY PROFICIENCY TESTING PER ANSI N13.11

Objective: Support the implementation of proficiency testing under criteria developed for ANSI N 13.11.

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; ANSI N13.11 for the NRC and an internal DOE standard for DOE. The most recent revision of ANSI N 13.11 incorporates both agency's requirements thus providing a single set of criteria for proficiency testing in the U.S. 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.

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. Three sources of radiation encountered within the industrial community are taken into account:

Accelerated 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.

Electron beam accelerators in the 100 to 300 keV range are sufficiently low in voltage such that they can be housed in lead shielding to provide the needed safety for operators from the resultant x-rays generated when electrons impinge upon target materials. These accelerators utilize elongated filaments and have been made at up to three meters in 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 A have been achieved. Since product through-put is proportional to beam current, production rates in excess of 700 m/min 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 125 keV and 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.

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

A diversity of other significant industrial operations employ mid-range, high current accelerators as part of manufacturing processes. For example, tire companies (Bridge-stone, Goodyear, Michelin) use such electron beam processing to partially cure tire components in extruded form before they are plied into tires, then molded and finally cured. Shrink film used in food packaging applications (Cryovac Division of the Sealed Air Corporation) and heat recoverable tubing (Raychem, 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 use in the sterilization of medical devices.

For the most part, the higher voltage, high current accelerators are being considered for developing markets wherein their higher beam penetration is of consequence (10 MeV

giving 3.5 cm electron penetration in unit density material). These markets include medical device sterilization, food irradiation (where experimental work is being conducted on food irradiation with 10 MeV electron beams at Iowa State University), and curing of fiber reinforced composite plastics. Only a few companies have demonstrated the capability of producing modest current, higher voltage electron beam accelerators.

No specific needs pertaining to accelerator design nor development will be 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.

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. 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.
- Ability to be scaled down for research purposes with a readily available installed base of research scale systems.
- Lower dose rates of approximately 10 kiloGreys 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 project 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 "National Needs Report" published in 1995. These have been totally revised for this report and are presented as MPD D.3.2 and MPD D.4.2 and reflect the status and needs as they now exist in 2001. Likewise, MPD D.5.1 is a thorough revision of the MPD on "Medical Device Sterilization" as is MPD D.7.1 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 the previous (1998) report has been dropped. 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. However, 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 nor proven commercial viability.

As a result, the Industrial Applications and Materials Effects sub-committee proposes four revised and up-dated MPDs in this report:

D.3.2 Radiation Hardness Testing and Mixed-Field Radiation Effects

D.4.2 Neutron Dosimetry for Reactor Pressure Vessel Surveillance

D.5.1 Medical Device Sterilization

D.7.1 Food Irradiation

In it, MPD D.5.1 presents the diversity of dosimetry methods that have been recognized by industrial organizations and associations.

MPD D.3.2: 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 NASA, and there is strong likelihood that the lack of availability of radiation-tolerant electronics will become a major stumbling block regarding the development of commercial and government-sponsored space communication and surveillance systems within the next few years. Accordingly, it is essential that a strong basis of personnel expertise and testing facilities be maintained in order to address this problem, if the U.S. is to maintain its current lead in space technology. Pertinent technical organizations, including NIST, NASA, universities having relevant research programs, and the appropriate organizations operating radiation facilities, must establish and maintain a close working relationship in order to meet future challenges.

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 operates a 3 MeV tandem NEC PELLETRON that has provided neutron beams of appropriate energy (from 0.2 to 4 MeV), and intensities (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 flux. More typical fluxes 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 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.

- 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 this Naval Surface Warfare Center**,** Sandia Laboratory, Rensselaer Polytechnic Institute Gaerttner Laboratory, 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.4.2: 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 (USNRC) has issued requirements designed to help ensure that the structural integrity of the reactor pressure vessel is preserved. In particular, fracture toughness requirements for power reactors, for both normal operating conditions and anticipated operational occurrences, are set forth in Title 10 of the Code of Federal Regulations, Part 50 (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities." In order to satisfy the codified fracture toughness requirements, 10 CFR 50 further requires that the operators of all commercial nuclear power stations institute a neutron dosimetry program that provides measurement data for material damage correlations as a function of the fast-neutron fluence.

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

detailed knowledge of the plant-specific geometrical and material configuration, as well as the physics describing the detailed behavior of neutrons within the reactor materials. Because of the importance of these calculations and the difficulty in performing them, qualification of the calculational method by comparing resultant fluence predictions to measurements must be made in order to ensure their accuracy and reliability. Calculation-to-measurement comparisons are also used to identify biases in the calculations, and to provide reliable estimates of the fluence uncertainties.

A significant amount of activity under the purview of MPD D.4.2, Neutron Dosimetry for Reactor Pressure Vessel Surveillance, has taken place. MPD D.4.2 has been extensively revised to reflect the current state of affairs regarding neutron-induced material embrittlement in reactor pressure vessels. In September 1996, NIST hosted a public meeting in which representatives from the commercial nuclear-electric-generating industry shared their ideas and concerns regarding USNRC draft regulatory guide DG-1053, Calculational and Dosimetry Methods for Determining Pressure Vessel Neutron Fluence, with 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. A new ANS standard dealing with the determination of RPV neutron fluence is also presently being developed. Several research endeavors are currently underway; 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.

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 1 person-year per year over the next three-year time frame.

MPD D.5.1: MEDICAL DEVICE STERILIZATION

Objective: Promulgate NIST Traceable Empirically Verified Protocols for Gamma and Electron Beam Dosimetry Used in 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 American Society for Testing and Materials (ASTM -- see www.astm.org) provide guidance to the practitioner of radiation sterilization to justify claims of product sterility and to do so within the context of GMP protocols.

Radiation, mainly in the form of gamma rays emitted from 60-Cobalt 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] and/or radiochromic dye films.[12] 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/s. 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 (e.g. 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 2000 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 Riso National Laboratory in Denmark and the film alanine dosimeters from Gamma Services. 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 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), and Riso National Laboratory in Denmark, 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, Riso, PTB, ISO 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 correlation between dose distributions predicted by various modeling and calculation techniques with empirical dosimetry data gain by irradiating diverse products inside of boxes. 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 – Acquisition by NIST of EPR instrumentation for thin film alanine dosimetry strips.

References:

[1] "Medical Devices, Current GMP Final Rule; Quality Systems Regulation," **Federal Register** 61 FR:52602-52662, October 7, 1996, Washington, DC)

[2] AAMI TIR 17:1997 – "Radiation Sterilization Material Qualification"

[3] AAMI TIR 8:1991 -- "Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices"

[4] AAMI/CD-1 TR 198WG22 (1Nov96) -- "Sterilization of Health Care Products -- Radiation Sterilization -- Variations of ISO Dose Setting Procedures in Relation to the Design of Verification Dose Experiments and Dose Audits"

[5] AAMI/CDV-1 TR 15844 (1Jun97) -- ”Sterilization of Health Care Products – Radiation Sterilization -- Selection of a Sterilization Dose for a Single Production Batch”

[6] AAMI/ISO TIR 13409 (1996) -- ” Sterilization of Health Care Products --Radiation Sterilization – Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Batches”

[7] AAMI/ISO TR 198WG203:1 – ” Sterilization of Health Care Products – Radiation Sterilization – Guide to Selection of an Appropriate Method for Establishing a Sterilization Dose”

[8] ANSI/AAMI ST60 (1996) – ”Sterilization of Health Care Products -- Chemical Indicators -- Part 1: General requirements”

[9] ANSI/AAMI/ISO 11137 (1994) – Sterilization of Health Care Products – Requirements for Validation and Routine Control -- Radiation Sterilization”

[10] ASTM E 1205-93 -- ”Standard Practice for Use of a Ceric-Cerous Sulfate Dosimetry System”

[11] ASTM E 1261-94 -- ”Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing”

[12] ASTM E 1275-98 -- ”Standard Practice for Use of Radiochromic Film Dosimetry System”

[13] ASTM E 1276-96 -- ”Standard Practice for Use of a Polymethylmethacrylate Dosimetry System”

[14] ASTM E 1310-94 -- ”Standard Practice for Use of a Radiochromic Optical Waveguide Dosimetry System”

[15] ASTM E 1400-95a – ”Standard Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory”

[16] ASTM E 1401-96 -- ”Standard Practice for Use of a Dichromate Dosimetry System”

[17] ASTM E 1538-93 -- ”Standard Practice for Use of the Ethanol-Chlorobenzene Dosimetry System”

[18] ASTM E 1539-93 -- ”Standard Guide for Use of Radiation-Sensitive Indicators”

[19] ASTM E 1540-93 -- ”Standard Practice for Use of a Radiochromic Liquid Dosimetry System”

[20] ASTM E 1607-96 -- ”Standard Practice for Use of the Alanine-EPR Dosimetry System”

[21] ASTM E 1608-94 -- ”Standard Practice for Dosimetry in an x-ray (Bremsstrahlung) Facility for Radiation Processing”

[22] ASTM E 1631-96 -- ”Standard Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations”

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

[24] ASTM E 1650-97 -- ”Standard Practice for Use of Cellulose Acetate Dosimetry System”

[25] ASTM E 1702-95 -- ”Standard Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing”

[26] ASTM E 1707-95 -- ”Standard Practice for Estimating Uncertainties in Dosimetry for Radiation Processing”

[27] ASTM E 1818-96 – “Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV”

[28] National Research Council. **An Assessment of the National Institute of Standards and Technology Measurement and Standards Laboratories – Fiscal Year 2000**; National Research Council; Washington, DC; pages 125 to 133.

[29] Miller, A. and Sharpe, P.H.G. “Dosimetry intercomparisons in European medical device sterilization plants,” **Radiation Physics and Chemistry**, Volume 59 (2000), pages 323-327.

MPD D.7.1: FOOD IRRADIATION

Objective: Establish NIST Traceable Protocols to Calibrate and Verify Dosimetry for All Aspects of the Food Irradiation Process

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

The efficacy, minimal effect on nutritive value and general safety of irradiating food has been demonstrated over and over again throughout the past three decades. The World Health Organization has long been on record as supportive of this method for treating food. However, in North America, there has been little practice of this proven method for enhancing the safety of foodstuffs. While several providers of contract gamma radiation services treat spices in bulk quantities which are then used in the preparation of a variety of food products, until recently there has been only one commercial source whose primary business is the irradiation of food products: Food Technology Services, Inc. of Mulberry, Florida. Starting in 2000, SureBeam Corporation, a subsidiary of Titan Corporation, opened electron beam irradiation facilities in Sioux City, Iowa, and Hilo, Hawaii, dedicated to food irradiation. Despite considerable misconceptions about consumer reactions, both Food Technology Services and SureBeam Corporation have had generally favorable response to their irradiated food products, providing safe and less perishable items to grocery stores, where in fact consumers have shown a preference for irradiated food products, clearly designated as such by an internationally agreed upon labeling. The reticence to accept this well proven process seems to be more on the part of major providers of food products than on the part of an informed public. However, that attitude is also changing. SureBeam has testing or marketing agreements with a number of large food processors including Zero Mountain Foods, Del Monte, Schwans, and American Foodservice Corporation. Also, IBP and Excel Corporation, which together process about 80 percent of U.S. ground beef, announced that they will begin test markets of irradiated beef soon.

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 has announced an alliance with SureBeam Corporation to operate a SureBeam system with electron beam and x-ray capability at a newly constructed facility on their campus at College Station, Texas.

Two sub-committees of the American Society for Testing and Materials (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 nine ASTM standards providing information about food irradiation:

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

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

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

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

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

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

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

ASTM F 1885-98 – "Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings 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 dose of 2.0 kGy, it has been shown that this microorganism is virtually eliminated in all forms of beef. The FDA (59CFR, pages 43848-9) has approved a maximum absorbed dose of 4.5 kGy for fresh red meat products which, assuming a 3:1 maximum to minimum dose ratio for radiation penetration, results in a minimum of 1.5 kGy exposure. It has also been shown that at the irradiation doses required for pathogen control, there is virtually no effect on the macronutrients (proteins, fats, and carbohydrates) in meats and that micronutrients (vitamins and minerals) are affected to about the same degree as they are when treated with other processes. At a maximum absorbed dose of 2.0 kGy, Vibrio species and the Hepatitis A virus are eliminated in oysters while not harming the live shellstock oysters. The FDA (see: www.fda.gov) lists a maximum absorbed dose of 1.0 kGy for irradiating fruits and vegetables to delay senescence and control arthropod pests and a maximum absorbed dose of 30 kGy for spice irradiation. Poultry can be irradiated to a maximum absorbed dose of 3 kGy.

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

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 radiochromatic dosimetry films and the evolving use of alanine dosimetry need to be reexamined within these prescribed dosimetry limits and ranges to assure that irradiated foodstuffs indeed meet these regulatory requirements. Likewise as food irradiation becomes an adopted process, there will be increased need to explain the protocols involving dosimetry traceability to a national standard to practitioners involved in the food industry.

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.

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

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.

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.5.1).

7 – On a research level, support investigation of the potential for x-ray conversion at 7.5 and at 10 MeV using alternative target materials for electron sources and conduct facilities design studies to provide practical guidelines on how to implement x-ray or bremsstrahlung irradiation in food processing.

Resource Requirements:

1 – A designated NIST contact is needed to coordinate various aspects of food irradiation and its implications on dosimetry calibration services. As the food irradiation process gains in commercial acceptance, a minimum of one person-year per year over the next three year time interval is needed.

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

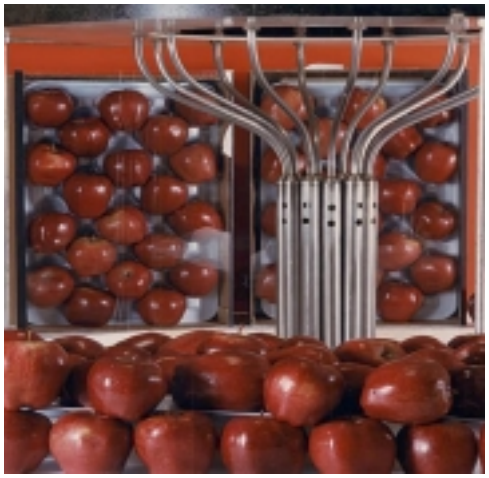

Figure D.7.1 – Apples to be gamma irradiated in a laboratory unit.

In Memoriam: This MPD was composed by Don Derr, retired USDA and food irradiation consultant, who passed away during 2000. Don made several presentations at CIRMS meetings and invaluable contributions to the understanding of the food irradiation process.

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, 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 PNL, 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 its 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.

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

Newsletter/Web Site: In the spring of 1994, CIRMS launched its own Newsletter. Under the editorial leadership of Bill Casson, the CIRMS Newsletter contains not only summaries of the organization's own efforts and activities, but also features a broad range of topics of general interest to entire ionizing radiation community. While setting an ambitious goal of being a quarterly, the CIRMS Newsletter has scaled back to being semi-annual. This use of conventional print media has been complemented by the development of the CIRMS web site: www.cirms.org. Bill has worked with Bob Loesch and Tom Slowey over the past couple of years to make this a more timely way in which CIRMS can keep its membership abreast of its activities. Following the annual meeting last fall, a summary of the meeting was quickly posted on this site along with color photos. The CIRMS web site opens the CIRMS forum to the Internet and all having access to the world-wide-web.

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 will 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. 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. Since then, the entire report has been converted into an

electronic format and made available on the CIRMS web site: www.cirms.org. The third "Needs Report" is issued in October 2001.

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 interacts with appropriate subcommittees within the American Society for Testing and Materials (ASTM) that deal with radioactivity measurements. The ORP subcommittee collaborates with the Health Physics Society (HPS). 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 31 workshops, averaging three or four per year. These workshops can also help 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.

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, being guided by then First Vice-President George Xu. At the annual meeting last fall, CIRMS presented five awards to students who presented summarizes of their work during the meeting. These are also highlighted on the CIRMS web site. This program will form an integral part of the annual meetings and will flourish with sustained sponsorship from some of CIRMS corporate members.

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. 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, three of 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 Tom Heaton and Past-President Larry DeWerd, the Public and Environmental Radiation Protection Subcommittee by Dave McCurdy and Ken Inn, and the Industrial Applications and Materials Effects by Roberto Uribe and Ken Koziol. Ken Swinth chairs the Occupational Radiation Protection subcommittee.

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:
Example of a Successful MPD

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

Summary

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

Detailed Program Characteristics

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

In the United States, the Food and Drug Administration's Center for Devices and Radiological Health (CDRH) is responsible for calibrating all the instruments that the govern-

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

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

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

U.S. Facilities, Staffing, and Funding

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

1. NIST: As indicated above, NIST needs major new resources in equipment and personnel to carry out this program. With the tight deadlines of MQSA, this program needs high priority. A minimum requirement is 2 person-years and $250,000 for each of two years.
2. CDRH: Most equipment for the new mammography facility has been ordered. Two additional person-years will be required: one to finish developing the automated computer system and the other to do routine calibrations, maintain in-house quality control, and maintain inventory. Equipment costs are estimated to be about $130,000 for each of two years.

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

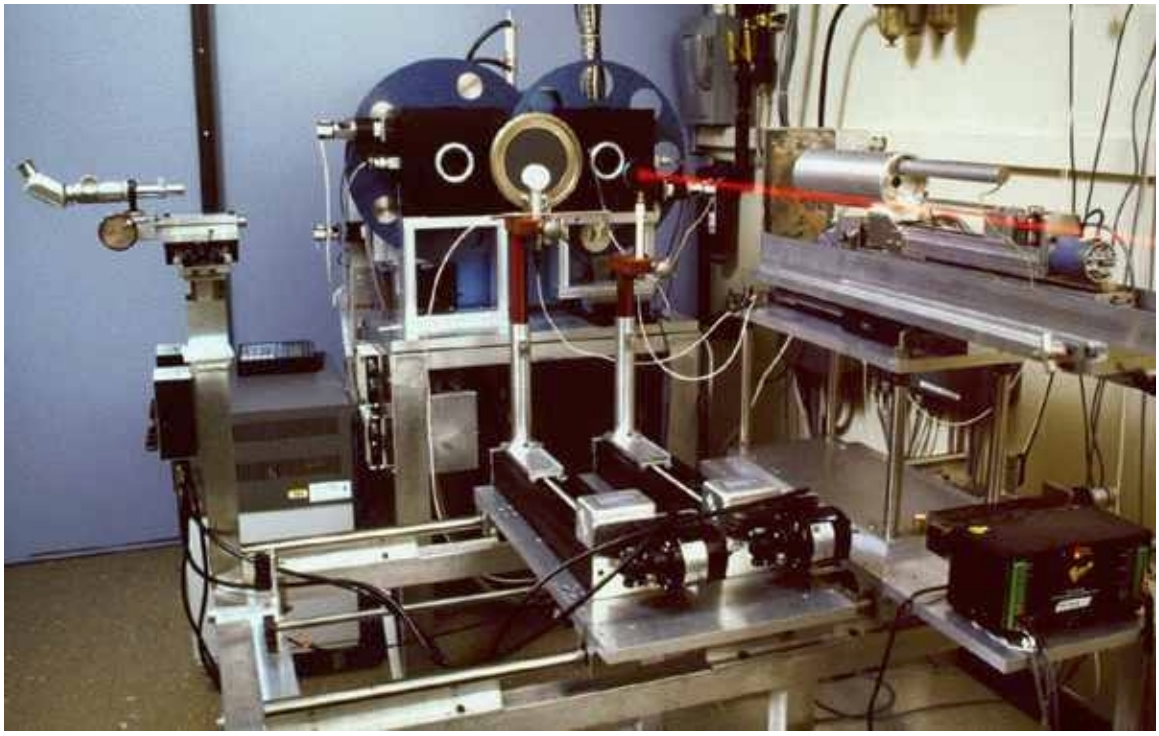

Figure A.1 – National standard calibration range for mammography testing.

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
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

Date	Topic	Subcommittee Interest
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

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

AECL—Atomic Energy of Canada Limited

ALARA—As Low As Reasonably Achievable

AML—Acute Myeloid Leukemia

ANSI—American National Standards Institute

ASTM—American Society for Testing and Materials

BOMAB—Bottle Manikin Absorption (Phantom)

BRMD—Bureau of Radiation and Medical Devices

CCD—Charge Coupled Device

CDRH—Center for Devices and Radiological Health

CEC—Commission of the European Communities

CERN—Centre European de Recherche Nucleaire

CIRMS—Council on Ionizing Radiation Measurements and Standards

CRADA—Cooperative Research and Development Agreement

CRCPD—Conference of Radiation Control Program Directors

DOC—Department of Commerce

DOD—Department of Defense

DOE—Department of Energy

DOELAP—Department of Energy Laboratory Accreditation Program

DOI—Department of the Interior

ED—Electronic Dosimeter

EML—Environmental Measurements Laboratory

EPA—Environmental Protection Agency

EPR—Electron Paramagnetic Resonance

FDA—Food and Drug Administration

FEMA—Federal Emergency Management Agency

FTE—Full Time Employee

GAO—General Accounting Office

GCRS—Ground Contamination Removal Systems

HPS—Health Physics Society

HPSSC—Health Physics Society Standards Committee

IAEA—International Atomic Energy Agency

IAME—Industrial Applications and Materials Effects

ICRP—International Commission on Radiological Protection

ICRU—International Commission on Radiation Units and Measurements

IEC—International Electrotechnical Commission

INEL—Idaho National Engineering Laboratory

ISO—International Organization for Standardization

LANL—Los Alamos National Laboratory

LED—Light-Emitting Diode

LLNL—Lawrence Livermore National Laboratory

LS—Liquid Scintillation

MAP—Measurement Assurance Program

MAPEP—Multi-Agency Proficiency-Evaluation Program

MARLAP—Multi-Agency Radiochemistry Laboratory Analytical Procedures

MARSSIM—Multi-Agency Radiation Survey and Site Investigation

MDL—Minimum Detectable Limits

MDRF—Materials Dosimetry Reference Facility

MIRF—Medical-Industrial Radiation Facility

MPD—Measurement Program Description

MQA—Measurement Quality Assurance

MQSA—Mammography Quality Standards Act

MRI—Magnetic Resonance Imaging

NASA—National Aeronautics and Space Administration

NCRP—National Council on Radiation Protection and Measurements

NDA—Nondestructive Analysis

NDA—New Drug Applications

NEI—Nuclear Energy Institute

NIST—National Institute of Standards and Technology

NMR—Nuclear Magnetic Resonance

NMS—Natural Matrix Standard

NPL—National Physical Laboratory (U.K.)

NRC—Nuclear Regulatory Commission

NRC-Ottawa—National Research Council

NSWC—Naval Surface Weapons Center

NVLAP—National Voluntary Laboratory Accreditation Program

ORNL—Oak Ridge National Laboratory

PCB—Polychlorinated Biphenyls

PCDF—Polychlorinated Dibenzofurans

PE—Performance Evaluation

PET—Positron Emission Tomography

PMMA—Polymethyl Methacrylate

PNL / PNNL—Pacific Northwest National Laboratory

PPT—Part Per Trillion

PTB—Physikalisch-Technische Bundesanstalt (Germany)

PWR—Pressurized Water Reactor

P2—Pollution Prevention

RESL—Radiological and Environmental Sciences Laboratory

RIMS—Resonance Ionization Mass Spectrometry

RPV—Reactor Pressure Vessel

SPECT—Single Photon Emission Computed Tomography

SRM—Standard Reference Material

TLD—Thermoluminescent Dosimeter

TRU—Transuranics

TWRS—Tank Waste Remediation Systems

UV—Ultraviolet

USDA—United States Department of Agriculture

VA—Veterans Administration

VOC—Volatile Organic Compounds

WAFAC—Wide-Angle-Free-Air-Chamber

WIPP—Waste Isolation Pilot Plant

October 2001

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