

# **Community Health Assurance Monitoring Program**

**(CHAMP)**

## **Radionuclide Biomonitoring Tests**

### **National Expert Perspectives**

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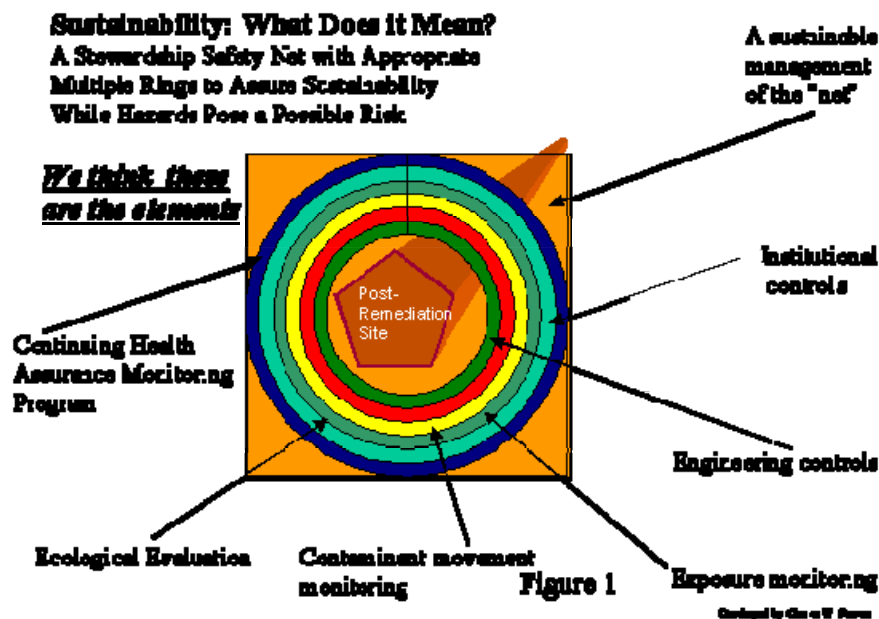
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## Background

A Community Health Assurance Monitoring Program (CHAMP) is designed to identify evidence of exposure or early health status changes in communities living in proximity to potentially hazardous sites such as industrial facilities or hazardous waste sites. The CRESP-CHAMP project has examined both the technical feasibility of various approaches to monitoring humans for exposure, as well as the context in which such a program could be implemented. The CRESP-CHAMP project specifically evaluated CHAMP as a component of a long-term stewardship system for residual radioactive or chemical waste at Department of Energy facilities. In CRESP's vision (see figure), a human biomonitoring program (CHAMP) was envisioned as an added ring of security in addition to engineering controls, institutional controls, environmental monitoring (contaminant movement), and ecological evaluation, to achieve a sustainable safety net or long-term stewardship.



This present document summarizes and integrates the information from interviews with several national experts on the analytical sensitivity and practical operational aspects of various tests applicable for population radionuclide biomonitoring. The report builds upon the CHAMP concepts noted in two prior reports developed by CRESP researchers (Friedlander and Gochfeld, 2005; Friedlander and Gochfeld, 2006), in which different

biological media and analytical techniques were reviewed for their potential applicability in monitoring populations potentially at risk of exposure to possible radiologic sources. These reports covered a broad range of approaches for the early detection of exposure to radionuclides in human populations. The general scenario was a Department of Energy site containing residual radioactive waste (or mixed rad-chemical waste) that was contained on site. The prospective populations included the general population residing near the site as well as future workers on the site. As sites become re-industrialized or converted to commercial uses, future workers will not be considered rad workers and will not have rad-worker training.

The first CHAMP report (October 2005) was a Technical and Feasibility Assessment of CHAMP as part of a Sustainable Long-term Stewardship Vision. The second report (April 2006) focused on detecting radionuclides for designing biomonitoring modules. Both reports were far ranging to explore new and promising as well as old and standardized analytical procedures. In these reports we considered the various radionuclides that would be commonly associated with the radiation waste from the production, testing, or dismantling of nuclear weapons. We also considered the different tissues and fluids that could be collected and analyzed as well as sensitivity and specificity..

These reports provide a rich resource for considering the pros and cons of initiating monitoring programs, as well as the approach to implementation. We focused our attention on a handful of analytic techniques that appeared to offer promise of detecting contamination at a very low level.

The prior two reports depended mainly upon published information in scientific journals and governmental reports. However, some monitoring considerations, such as choosing the appropriate type of biological sample for specific radionuclide biomonitoring needs, selecting the type of radioanalytic methodology for sensitive levels of detection, and assessing test feasibility (such as test availability, public acceptance, approximate costs) were less clearly represented in the published domain. Furthermore, a number of assumptions were involved in drafting a set of potential biomonitoring tests applicable for given populations, such as noted in our prior report (Friedlander and Gochfeld, 2006) and shown in table 1. Expert opinions regarding test selection was needed.

It was therefore planned to interview experts experienced in the analytical technologies and their application to human populations to obtain useful information and guidance. This report summarizes the findings from several interviews undertaken in early summer 2006.

Table 1: Possible Off-Site Population Biomonitoring Test Set for Radionuclides.

Biological Sample	Radionuclide	Analytic Test	Comment
Teeth	Sr-90	EPR	<i>In vivo</i> EPR in the future.
			<i>In vitro</i> EPR currently used, but not highly sensitive or specific.
Urine	Pu-total Pu-239,240	AMS	Good isotopic measures, highly sensitive,
	Uranium-total	ICP-MS	Currently available, moderately sensitive
	Am-241	Alpha-spectrometry	Eichrom TRU enhancement, moderately sensitive
	Cs-137	Gamma spectrometry	Good sensitivity
Whole Body	Cs-137	WBC	Good sensitivity and specificity
	Co-60		
	Am-241		

WBC: whole body counting EPR: electoparamagnetic resonance AMS: atomic mass spectrometry.  
FTA: Fission track analysis

## Biomonitoring: Retrospective & Prospective Approaches

The monitoring of populations for biological evidence that exposure has occurred can be influenced by a number of factors, each of which needs to be taken into consideration in the planning of a biological sampling program targeting a specific set of likely exposures (Etherington et al, 2004). These considerations and the details of several analytic methods were presented in the previous reports (Friedlander and Gochfeld 2005, 2006). While it is beyond the scope of the current paper to review the details of such considerations, it should be noted that different types of biological monitoring tests tend to reflect information over different periods of time after exposure.

### Temporal Considerations

Some measurement techniques reflect permanent and cumulative retrospective records of exposure or cumulative dose, while others are used prospectively and typically measure current or recent exposures. For example, electron paramagnetic resonance (EPR) tests on teeth integrate radionuclide dose (primarily gamma radiation) over the length of time

that the individual has possessed the measured tooth. For children, EPR analysis of shed deciduous teeth can integrate dose over the first few years of life, while for adults an analysis of secondary teeth may integrate dose over the rest of a lifetime. When properly conducted, EPR analyses can determine whether a certain cumulative level (from gamma and hard beta radiation) has or has not been encountered by an individual over a lifetime. This assessment can be done while the person is alive or even several hundred years later. It can be performed *in vivo* while in a dental-type chair or *in vitro* on teeth that have been shed or extracted. This cumulative dose is a powerful assessment, not available through measurements in blood, exhaled air, hair, urine or feces. EPR “represents the only reliable method that is able to reconstruct external gamma radiation doses individually, at a reasonable dose level and over long periods of time” (Romanyukha et al, 2005; ICRU, 2002). In addition, serial EPR measurements may indicate changes from baseline, thus also providing trend information in populations. This method measures mainly external radiation and needs to adjust for the effect of solar radiation.

A different type of time integration of exposure is represented by biological samples of hair or nail clippings. These samples tend to reflect the retention of exposures over weeks to months, but do not integrate over the years or decades represented by EPR.

Shorter-term patterns of biological exposure for many agents can be assessed through the evaluation of blood or urine specimens. The levels of any radionuclide in blood or urine depend on their toxicokinetic characteristics. These types of specimens may reflect nearly real-time concentration trends after initial exposure to rapidly absorbed and excreted materials. The typical biological monitoring of alpha emitting radionuclides in humans usually includes analyses of urine concentrations.

### **Interpretation and Communication**

Regardless of whether retrospective or prospective biological monitoring is applied, there is likely to be the issue of addressing uncertainty in results. Recent guidance in biological monitoring approaches have been developed to take into account a range of uncertainties that may arise from variations in intake patterns, times of monitoring in relationship to intake, absorption parameters, degree of retention, excretion patterns, and analytical measurement attributes (ICRP, 1997; Etherington et al, 2004). The international biological monitoring approach recommended for occupational exposures is designed to meet a minimum requirement that the assessed dose be underestimated by no more than a factor of three (ICRP, 1997). A similar type of standard or guideline was not found for assessing biological exposures in general populations or communities – i.e., groups where concentrations are likely to be substantially lower than occupationally exposed workers. At low concentrations it is feasible that assessed doses might exceed a range of three for underestimation, since technological limitations may fail to detect very small exposures. There is no standard criterion for identifying how much elevation above background, may indicate a new radiation exposure. The biomonitoring programs discussed in the interviews include a one-on-one interpretation of results to each subject based on their individual as well as collective analytic results

## Methodology

Based upon the prior two reports on Community Health Assurance Monitoring Programs (Friedlander and Gochfeld, 2005; 2006), the authors had identified a substantial literature regarding human radionuclide biomonitoring. Table 2 outlines some of the key radionuclides of interest sorted by type of biological sample and the interviewees involved in each activity. This table served as a useful point of departure to identify possible advisors and organize several telephone interviews. The advisors, all active researchers, were mostly selected based upon having recently studied or monitored human populations for radionuclides, having an analytical laboratory based in the United States and having had the demonstrated capability to detect low levels of radionuclides in at least one human biological sample media (including whole body counts). It should be noted that some of the selected researchers have applied analytical techniques uniquely available in their laboratories (AMS; *in vivo* EPR), while other researchers have developed more generally-applicable enhancements to somewhat more widely available assessment tools (MC-ICPMS). The interviewees (and **some** populations they sampled) were:

- Dr. James Conca, New Mexico State University in Carlsbad (WIPP neighbors)
- Dr. Terry Hamilton, Lawrence Livermore National Laboratory (Marshall Islanders)
- Dr. Melissa McDiarmid, University of Maryland Medical School (Gulf War veterans with depleted uranium fragments)
- Drs. Alex Romanyukha and Chad Mitchell, Uniformed Services University of Health Sciences (Mayak workers and Techa River residents)
- Dr. Harold Swartz, Dartmouth Medical School (*in vivo* EPR under development)

Table 2: Selected human radionuclide biomonitoring researchers relevant to specific radionuclides measured through types of biomonitoring samples

	Urine	Teeth	Whole Body/lungs
<sup>60</sup> Co			Conca
<sup>137</sup> Cs			Conca; Hamilton
<sup>90</sup> Sr		Romanyukha	
<sup>152</sup> Eu			Conca
U-total	McDiarmid;Conca		
<sup>234</sup> U			
<sup>238</sup> U	McDiarmid;Conca		
<sup>235</sup> U	McDiarmid;Conca		
<sup>238</sup> Pu			Conca
<sup>239</sup> Pu	Hamilton		Conca
<sup>240</sup> Pu	Hamilton		
<sup>239+40</sup> Pu	Hamilton;Conca		
<sup>241</sup> Am		Conca	Conca
Total gamma/beta		Swartz; Romanyukha	Conca

We developed a set of general questions and used these as a script for the interviews, although respondents were encouraged to answer broadly, and many responses were open-ended.

The respondents were given a very general scenario----a former DOE nuclear weapons facility with high levels of radioactive waste contained on site. Some of the site may be re-industrialized, resulting in a pool of workers without rad-training. Sites may also have fence line neighbors concerned about exposure to radiation through air, water or contaminated soil. The unique feature of the scenario was that the putative exposure might occur some time in the future. Most existing programs screen individuals with a known or suspected past exposure. These programs compare results to some risk-based or regulatory-based standard, whereas the CHAMP would look for a future change from baseline.

The hypothetical site was assumed to have a long-term stewardship program that included regular and required inspection of the containment system (usually a cap), as well as environmental sampling. The human biomonitoring can serve as a more sensitive and specific measure of human exposure.

The current set of interviews focus on *in-vivo* radionuclide analytic test capabilities (whole body and lungs; mouth/dental) and on selected *in-vitro* tests of urine and teeth. Topics of interest in the interviews included, but were not limited to, the expert's experience in:

- 1) Analytical tests useful to detect low levels of radionuclides in biological matrices;
- 2) Sampling and analytical issues relating to community radionuclide biomonitoring;
- 3) Potential emerging technologies or anticipated improvements in current ones

For each of the selected experts, a preliminary email was sent explaining who we are, our interest in long-term human exposure biological monitoring for environmental radionuclides, the context for our surveillance interests, and some topics that might be covered in a telephone conference call (see example, Attachment 1). Email communication identified a mutually acceptable time for an hour-long conversation, in which both authors participated.. Notes taken during the interview, after confirmation by each of the authors, form the basis for the following general findings.

## **Results**

### **1. *In-vitro* EPR (measurements in shed or extracted teeth)**

The *in-vitro* EPR (discussed with Drs. Romanyukha and Mitchell of the Uniformed Services University of the Health Sciences, and Swartz of Dartmouth), has better sensitivity – currently down to about 20 mGy. The theoretical detection limit is about

0.46 mGy, and labs could improve in the future upon the current 20 mGy level. The procedure can be applied to collected samples of human or animal teeth (such as cow teeth), so that ecological surveillance could potentially supplement human assessments. The technique is “used all over the world” and a 4<sup>th</sup> series of international laboratory performance comparisons just having been completed. Many universities have EPR equipment, but the only United States laboratory participating in the most recent international interlaboratory comparison of EPR tooth dosimetry was the USUHS laboratory. The experts stated that *in vitro* EPR could be a useful monitoring tool in populations near nuclear waste sites – particularly if defined cohorts were followed. They think that the cumulative human measures through EPR would have less uncertainty than those derived through the set of assumptions applied from environmental monitoring results. This is an important concept, meriting further consideration and validation. Workers and site neighbors cannot be expected to donate teeth for this purpose. However, shed deciduous teeth of children such as the “Tooth Fairy Project” could be valuable for reassurance. The technology also raises the possibility of using tooth or tooth-like structures analogous to radon monitors. Currently the sensitivity is not low enough to detect exposure due to slow leakage of radioactive substances from a containment failure.

## **2. *In-vivo* EPR (measurements while the test subject waits)**

The *in-vivo* electro-paramagnetic resonance (EPR) assessment of radionuclides in teeth is still in its early stage of development, exists only at Dartmouth, and is not yet ready for wide scale applications. Dr. Swartz (Dartmouth Medical School) currently is able to measure a person’s radionuclide exposure of 300cGy or less to teeth through a 15 minute (the goal is 5 minutes) dental measurement. The approach is not sensitive to alpha radiation, but readily detects total contributions from Cs-137 and Sr-90. *In vivo* EPR is expected to be a useful tool for responding to emergency situations. It will be possible to quickly determine whether or not high doses have resulted from accidents or terrorism to targeted groups, such as nuclear workers or members of emergency response teams. Although many university chemistry departments have EPR units, very few are currently used for human radiation biomonitoring. While exposure detection levels can be reduced (or sensitivity enhanced) by increasing measurement time and improving software, this method is not yet sensitive enough for epidemiologic community studies or low dose-assessments. Dr. Swartz is embarking on a long-term prospective study measuring EPR in teeth still in the mouth, which will enhance the value of this modality for long-term monitoring of individuals. He envisions developing a mobile unit.

## **3. Whole Body Monitoring (measurements while the test subject waits)**

The Carlsbad Environmental Monitoring and Research Center (CEMRC) at New Mexico State University has been providing *in vivo* whole body counting and lung counting to people living near the Waste Isolation Pilot Plant (WIPP) in Carlsbad, New Mexico. Screening began two years before WIPP opened, and has continued for nearly 10 years after the opening. This makes it unique in having the only “before and after” radionuclide whole body data in the world, and it has effectively utilized such



measurements to communicate with and to reassure the public. In unexposed individuals the main signal is from naturally occurring potassium-40. The method is particularly sensitive for gamma emitters (e.g. cesium-137), but can measure strontium-90 via the gamma emitted by its daughter yttrium-90. The CEMRC laboratory also analyzes urine and feces samples to capture the alpha emitters. Whole body counting takes about 30 minutes for optimal measurement, although shorter time is feasible. In addition to the fixed whole body counter, which is state of the art and one of the best units in the world (partly due to pre-World War II metal shielding), the site also owns a 57 foot mobile unit, which was used at Rocky Flats for nearly one and one-half years. The CEMRC has counted approximately 1000 people.

Marshall Islands residents have also been assessed with whole body counting for Cs-137 exposures, which are of some concern because of the consumption of locally grown coconuts which preferentially take up the radionuclide through coral soils. The Marshall Islanders readily accept such monitoring, and are receptive to discussions of test results. The interview results indicated that whole body counting was a feasible stand-alone monitoring program, operating much like historical Tuberculosis Screening mobile units, we explored logistics. In practice a WIPP counting session takes 30 minutes followed by a 30 min interpretation Q and A session, while the next person is in the counter. It would be reasonable to count about 12-16 people a day, or about 72-96 people in a six day week.

Considering other requirements for the mobile unit, it might be available for about three months of the year (12 weeks), allowing counting of almost 100 people in about 10 communities. Cost information was only informally discussed. The mobile unit is operated by a staff of two CEMRC employees. We envision a driver-maintenance person and an instrument-operator/risk communicator person. Including equipment maintenance and truck operation expenses, the overall cost of whole body counting should be relatively modest and is not likely to be a limiting factor for serious monitoring efforts of several populations on an annual basis. In addition to the mobile unit, the DOE system may have as many as 12 whole body monitoring systems currently operating at various sites, currently used for workers. The availability for monitoring other populations can be explored.

#### **4. Analysis of Radionuclides in Urine**

Dr. Hamilton reported that the DOE requires that the public not be exposed to a 50 year committed dose of 100 mrem above background (or 15 mrem using Superfund Cleanup Criteria). However measuring evidence of such low levels in populations has been beyond the capability of traditionally available biological monitoring techniques. Dr. Hamilton provided information on the Accelerator Mass Spectroscopy (AMS) analyses at the Lawrence Livermore National Laboratory which can now reach the needed analytical sensitivity level. A sensitivity of 1 uBq (microbecquerels) would approach cleanup limits (about 10 mrem committed over 50 years), and the current AMS technology can detect <sup>239</sup>Pu at about 0.2 uBq. AMS is being used to biomonitor urinary plutonium in Marshall

Island's residents as they move to resettle ancestral homelands from which they were evacuated during Cold War nuclear testing. Plutonium is of the greatest public concern in the Marshall Islands, even though Cs-137 is probably a greater exposure risk there (see Whole Body Monitoring).

The median urinary excretion of  $^{239}\text{Pu}$  in the more than 300 people measured in the Marshall Islands is about 0.2 uBq. No comparable data is available for mainland United States residents, so it is unclear as to whether that level is greater than one might expect. However, the levels appear to be higher in older residents – either reflecting higher exposures in the past or accumulation of exposure over a longer time period.

AMS is currently only available at LLNL, within the United States, although the Australian National University also has it – and it was initially developed there. LLNL currently spends about \$1400 per AMS sample because of high fixed facility costs and modest sample throughput. It has a much larger capacity, and with routine running of samples could substantially reduce the per sample costs. The equipment is rugged, doesn't have interference issues (as with some other analytical techniques), can run 64 targeted measurements in 24 hours, and doesn't suffer from analytical drift. Pu-239, 240, 241, and 244 can be measured through AMS. It can be used to also distinguish natural from anthropogenic uranium. It can specifically measure U-236, which is indicative of reprocessed uranium.

When asked if LLNL could handle the additional AMS monitoring for approximately 500 people, the response was an emphatic “yes”. It would welcome the opportunity to expand its use of AMS. LLNL has the “most productive AMS facility in the world”, and is oriented toward doing a range of measurements on a large scale.

The ICP-MS urinary analyses of uranium (McDiarmid) could reach 1 ng/g creatinine. Isotopic analysis was feasible only if total uranium exceeded 10 ng/g creatinine. While 24 hour urine samples are preferable, it is entirely feasible to use 8 hour collections with creatinine standardization. The Armed Forces Institute of Pathology (AFIP) and the University of Cincinnati (NIOSH lab) have provided urinary uranium evaluations using ICP-MS. Costs via AFIP are reported as approximately \$100 to 150 per test for total uranium, and are an additional \$200 or so for isotopic analysis. This technique is also being used for Fernald workers.

### **Comparative Data**

All of the proposed techniques have had relatively restricted applications in the past, so that few population baselines are available. Each biomonitoring program will establish its own baseline in the early years of implementation. In addition, other health assessment programs, such as NHANES may incorporate some of these studies to provide general population reference data (Friedlander and Gochfeld 2005). Indeed, if outside funding were available, NHANES might expand its analytic testing program to include some of these new modalities.

## **Risk Communication and “Peace of Mind”**

A biomonitoring program that makes direct measurement of radiation exposure of individuals, can effectively provide reassurance to both future site workers and site neighbors that they are not being exposed above the ambient background level. Interviewees recounted this experience for both the Marshall Islanders and the WIPP neighbors.

## **Source Attribution**

In the event that an ongoing human biomonitoring program detects new elevations above the program background of one or more radionuclides in one or more individuals, it becomes necessary to identify the source of such recent exposure. The first step will probably involve a confirmatory or repeat testing. If elevation is confirmed, this will be followed by an exposure assessment to identify the pathway(s) by which such increase may have occurred. Personal and occupational histories would be obtained to rule out dietary, medical or workplace exposures. Spatial epidemiologic methods would be applied in the event that more than one individual shows an elevation. Both the biomonitoring as well as the environmental monitoring would be expanded, to identify whether the elevation is attributable to containment failure.

## **Conclusion**

The initial CHAMP concept was to integrate a biomonitoring scheme into an existing health maintenance program that might be provided by primary physicians or Health Maintenance Organizations (HMOs). It now appears that a free-standing voluntary program tailored to the site characteristics and local demography, would be feasible. The two methods offering the greatest sensitivity and ability to detect an unanticipated exposure are whole body counting and accelerator mass spectrometry of urine. In both cases economy of scale can be achieved to lower the unit costs. Both of these modalities are currently available and it would now be reasonable to include human biomonitoring in any discussion of long-term stewardship for DOE or other sites with residual contamination contained on site. The CRESPP concentric ring model includes human biomonitoring as one component of an integrated safety program. It is also apparent that these biomonitoring programs can provide reassurance to target populations that excess exposure above our natural radiation background has not or is not occurring.

## **Recommendations**

**The CRESPP vision for a multi-disciplinary comprehensive sustainable safety net should be incorporated into the long-term stewardship plans for DOE sites.**

**Whole body counting (WBC) coupled with sensitive urine analysis (AMS) would be suitable **test components measuring different radionuclides**, of a CHAMP as part of a sustainable stewardship program.**

**The planning for closure of DOE (or other sites) which will have contained residual nuclear materials should include consideration of a CHAMP in conjunction with engineering and institutional controls and environmental monitoring. The human biomonitoring has sufficient sensitivity to provide evidence of new exposures or continued reassurance.**

**A model CHAMP should be coupled with a site-specific appropriate response program for investigating any exposure that is detected. This response program might best be developed within the context of the early stages of a small site pilot CHAMP project.**

### **Acknowledgements**

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ATTACHMENT 1: Content of Initial Communication with Experts



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September 5, 2006

Dear Dr. R:

We are environmental physicians at the Environmental and Occupational Health Sciences Institute, a joint institute of Robert Wood Johnson Medical School and Rutgers University (New Jersey-USA) who participate in a multi-university project (CRESP) related to U.S. Department of Energy sites (see [www.cresp.org](http://www.cresp.org) web site for additional information).

Currently we are reviewing the feasibility of alternative approaches to long term human biomonitoring for environmental radiation exposure (including but not limited to nuclear waste sites, nuclear accidents). We view human monitoring as complementary to environmental monitoring. We have had the chance to review many reports and publications of human screening programs for radiation exposure, including a number of new and evolving technologic approaches, which offer the promise of enhanced sensitivity. We have read several of your published studies regarding population radionuclide assessments utilizing EPR technologies and new photostimulable phosphor imaging enhancements.

We would appreciate the opportunity to discuss with you in the next few days some aspects of your work relating to the assessment of communities near potential radiation sources and potential future technical enhancements that you might envision within the next decade or so.

Attached is our CONTEXT for surveillance as well as some topics we would like to consider.

Sincerely yours,

**Barry Friedlander and Michael Gochfeld**

**Barry Friedlander, MD, MPH and Michael Gochfeld MD, PhD**

ATTACHMENT  
DRAFT IDEAS FOR DISCUSSION

THE CONTEXT FOR SURVEILLANCE

The U.S. Department of Energy is remediating and “closing” many of its former weapons manufacturing sites, and entering them into a “legacy-waste management” program which potentially includes long-term monitoring of the environment, former workers, and site neighbors.

There has been substantial research and practical programmatic experience with human screening programs, but there is little consensus on the design of such a program or their utility much less on their cost-effectiveness.

Our own experience is in long-term monitoring of communities exposed to hazardous waste sites or contaminated drinking water.

Historically most surveillance programs have addressed populations with a known exposure (A-bombs, former workers, Chernobyl, Marshall Islands, etc). In these cases exposure occurred at a prior time period and declined. The proposed surveillance approach aims to detect a future exposure occurring at an unknown time period (hopefully never), compared with a prior background. Thus most programs have looked for exposure above some acceptable level while possible future surveillance may attempt to detect exposure to some level above “background” and attributable to a specific source.

GOAL FOR A HUMAN EXPOSURE BIOMONITORING PROGRAM

Early detection of exposure to radionuclides linked to a known or suspected source of contamination.

SUSTAINING HUMAN BIOMONITORING

Maintain long-term (indefinite?) program even when engineering or environmental monitoring do not detect evidence of an exposure pathway or “leakage”.

SOME TOPICS FOR DISCUSSION

Target radionuclides (which ones to study?)  
Biomonitoring media (including both *in vitro* and *in vivo* methods)  
Measurement techniques (e.g. accelerator mass spectrometry; ICP-MS, EPR, spectrometry, etc)  
Technical feasibility and reliability  
Identify tests with appropriate sensitivity and specificity

Identify new or emerging technologies  
Cost effectiveness and availability  
Population acceptability  
Quality assurance  
Interpretation of results  
Risk communication to participants and regulators and overseers  
What institutions are required to sustain a potentially costly, but continually “negative” program.