



NIOSH

NIOSH
Research Issues Workshop:
Epidemiologic Use of
Nondetectable Values in
Radiation Exposure Measurements

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Abstract

The Health-Related Energy Research Branch of the National Institute for Occupational Safety and Health (NIOSH) held the first of several planned workshops to determine the optimal use of current and historical exposure/dose data for use in epidemiological studies of radiation-exposed workers. The participants in this workshop examined procedures for interpreting nondetectable and erroneous values in occupational radiation exposure records. Presentations by invited speakers provided a basis for discussing methods for interpreting results from radiation dosimeter and bioassay measurements which were recorded as zero or adjusted in some manner by past administrative practices. Changes in interpretation and definitions for detection limit have an impact on the manner in which results were recorded and how they should be interpreted for epidemiologic purposes. Also, personnel dosimetry methods and procedures at Department of Energy facilities have changed significantly over time with the improvement in radiation measurement technology. Likewise, changes in record keeping procedures necessitate that special methods be developed for interpreting nondetectable results. Pocket ionization chamber measurements were suggested as one method for supplementing historical results of film dosimeters. Other proposed methods included the use of probability distributions and Bayesian statistics to estimate the frequency with which results would occur below the administrative limit or minimum detectable dose. This workshop provided an opportunity to

review past health physics dosimetry measurement and record keeping practices and to discuss new methods for interpreting historical measurements for use in epidemiologic studies. Several recommendations were made for topics for future workshops.

Background

During World War II the top secret Manhattan Project combined the nation's most elite scientists with military leaders to produce the first atomic bomb. Development of this nuclear device required an enormous amount of resources as well as scientific and technical efforts. Thousands of square miles spread across thirteen states served as principal development and production sites, making this effort a success in terms of national security. These sites are referred to as the Weapons Complex, employing over a half a million workers since the mid 1900s. Many of these facilities were involved in several operations including weapons research and development, nuclear materials productions, warhead component production, warhead testing and waste disposal, (see Table 1).¹

Although these facilities have much in common, there is no "typical" facility with regard to exposure potential. Each site has a unique combination of hazards that shape its particular exposure problems. Exposures to both chemical and physical agents occur at most facilities, but the type and degree of exposures have varied over time and from site to site. Practices for reporting occupational exposures have also

TABLE 1¹
The Dept. of Energy Weapons Complex (Principal Facilities)

Type of Facility	Facility	Location (State)	Size (square miles)	Approximate current employment
Weapons Research and Design	Los Alamos National Laboratory	NM	75	7,400
	Sandia National Laboratory	NM	62	8,500
	Lawrence-Livermore National Laboratory	CA	12	8,500
Materials production	Hanford Plant	WA	570	13,500
	Savannah River Site	SC	300	20,000
	Fernald	OH	0.2	1,000
	Idaho National Engineering Laboratory	ID	893	10,500
Weapons manufacturing	Rocky Flats Plant	CO	14	6,000
	Oak Ridge Reservation	TN	58	16,500
	Mound Plant	OH	0.3	2,400
	Pinellas Plant	FL	0.2	2,000
	Kansas City Plant	MO	0.5	7,800
	Pantex Plant	TX	14	2,800
Warhead testing	Nevada Test Site	NV	1,350	8,400
Waste disposal	Waste Isolation Pilot Plant	NM	16	650

SOURCE: Complex Cleanup.

varied over time from site to site due to several factors:

- Measurement technology limitations.
- Administrative practices.
- Regulatory compliance requirements.
- Security measures (classified materials).
- Record keeping practices.

- Lack of overall direction or standardization for such a program.

These factors resulted in dosimetry data which, as recorded, are biased in some manner. At some facilities many workers' dosimeters were read weekly, and during some periods, film dosimeter results less than the minimum detectable level were set to zero.² In other instances, a reading at or

below this subjective detection limit was recorded as an exposure or a dose at that limit to ensure that cumulative exposures or doses were not underestimated.³ A third way of recording non-detectable results was to assign some other "administrative" value such as half the minimal detectable level or a value selected by an established procedure.⁴ All of the above factors affect the quality and content of historical exposure data. The influence this type of data has on bias and misclassification, and recommended methods for treatment and use of these data in epidemiologic analysis has been the subject of discussion by several authors.^{2,3,4,5,6,7,8,9} Knowledge about these factors, ways to record dose results, and the methods to treat and use these data are required to accurately assess doses used for risk estimation in epidemiologic studies. All of this information served as the center of discussion for this workshop.

Introduction

The Department of Health and Human Services (DHHS) is responsible for managing and conducting both community and occupational epidemiologic studies at Department of Energy facilities. This responsibility was transferred to DHHS through a Memorandum of Understanding between the two agencies in late 1990. The National Institute for Occupational Safety and Health (NIOSH) is the agency within DHHS that is responsible for studying the relationships between health outcomes and occupational exposures to radiation, chemicals, and other hazards at these facilities.

Historical records and accurate exposure assessments of various hazards play a vital role in these studies. Changes in measurement technology, administrative practices, regulatory requirements, protection philosophy, and security measures have occurred throughout a fifty-year time period. Every one of these aspects may influence the accuracy and reliability of exposure estimates used in current and future epidemiologic studies.

NIOSH has initiated a project called "Research Issues Workshop" to address these changes specifically and to determine how they might affect exposure estimates used in epidemiology. This project is conducted through a series of workshops which bring together recognized experts in dosimetry, epidemiology, biostatistics, and exposure assessment. A workshop setting was chosen because of its inherent flexibility and ability to involve more scientists in creative problem-solving discussions. This paper serves as a summary of the proceedings from the first workshop sponsored by NIOSH in September 1993.

Objective

The objective of the first workshop was to determine the optimal use of "censored" or "non-detectable" radiation monitoring data in future epidemiologic studies of radiation exposed workers. Several speakers from various disciplines presented talks which served as a basis for discussion on this topic. The presentations covered four main areas:

- ① Historic uses of non-detectable data in epidemiology.
- ② Historic overviews of both internal and external monitoring methods.
- ③ Detection limit quandary and missed dose concepts.
- ④ One solution/approach used on an Oak Ridge cohort.

- Change in sensitivity of method over time.
- Changes in sampling methods over time.
- Quantitative vs. qualitative methods.
- Effects of sampling frequency.

Workshop Issues

Prior to the workshop, several technical issues related to the assessment of occupational radiation exposures were identified. Listed below are specific concerns on external and internal exposure data affecting exposure assessment strategies used for epidemiologic purposes.

External Exposure Data

- Changes in dosimeters and detection limits over time.
- Identification/separation of true zero dose results from true positive results.
- Impact of dosimeter exchange frequency upon measurement sensitivity.
- Imputation strategies (e.g., simple one value, multifactor, or stochastic approach).
- Site-specific practices (detection levels, energy response).

Internal Exposure Data (urinalysis and in vivo measurements)

- Methods for analyzing different radionuclides.
- Identification of true zero results from censored results.

Arrangement of Workshop

NIOSH is attempting to establish methods and procedures to be used in interpreting historical occupational exposure data that may have been censored or recorded as zero for use in epidemiologic analyses. The workshop was arranged in a manner to review each of the main areas listed in the objective and to address these technical issues. This served three purposes. First, it provided the workshop participants with a baseline for interpreting past dosimetry results from these facilities. Second, it served as a foundation for discussing how these results should be addressed in epidemiologic studies. And finally, it allowed NIOSH researchers to become familiar with the radiation monitoring and record keeping practices and procedures used at different times and at different facilities throughout the DOE complex.

The term Limit of Detection (LOD) as used in this document is defined as the smallest reading which can be distinguished from a background reading based on stated statistical assumptions. LOD may then be equated with detection level, minimum detectable activity, or minimum detectable dose. The term LOD is used throughout this document for consistency and the phrases "use of non-detected values" or "less than the LOD" or

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variations thereof means that any result meeting this criteria are below some threshold level.

Workshop Attendees and Speakers

The workshop attendees and speakers represented several areas of expertise including internal and external radiation dosimetry, biostatistics, epidemiology, health physics, industrial hygiene and radiochemistry. Table 2, lists the workshop attendees.

The presenters and respective topics were:

Dr. Jim Ruttener, Historic uses of non-detectable data in epidemiology;

Mr. Herb Meyer, Historic overviews of external monitoring methods;

Mr. Bill Moss, Historic overview of internal monitoring methods (specifically plutonium radiochemistry);

Dr. Allen Brodsky, Detection limit quandary and missed dose concepts;

Dr. Steve Wing, External Exposures at ORNL and their Implications for Epidemiology

Dr. Ed Frome, One solution/approach used on an Oak Ridge cohort.

Following each presentation a brief question and answer session was held to assure a basic understanding of the presented material. Miscommunication among scientists with different backgrounds is not uncommon since much of the same vocabulary may have different meanings to each profession. For example, the word "valid" can be interpreted by health physicists to mean that a result is true or accurate, but an epidemiologist might interpret it to mean that an approach is justified or acceptable.

TABLE 2
Workshop Attendees

Name	Expertise	Organization
Dr. Richard Hornung	Biostatistician	NIOSH
Dr. Anne Fidler	Epidemiologist	NIOSH
Mr. Larry Elliott	Industrial Hygienist	NIOSH
Dr. Thurman Wenzl	Industrial Hygienist	NIOSH
Dr. Steve Ahrenholz	Industrial Hygienist	NIOSH
Mr. Samuel Glover	Health Physicist	NIOSH
Mr. John Cardarelli	Health Physicist	NIOSH
Dr. Henry Spitz	Health Physicist	NIOSH
Ms. Janice Watkins	Biostatistician	ORAU
Dr. Ethel Gilbert	Biostatistician	PNL
Mr. Bill Tankersley	IH / HP	ORAU
Mr. Hap West	Health Physicist	ORAU
Mr. Bill Moss	HP / Radiochemistry	LANL
Dr. Allen Brodsky	IH / HP	Consultant
Dr. Daniel Strom	Health Physicist	PNL
Mr. Larry Tomczak	Statistician	FERMCO
Mr. Jack Fix	Health Physicist	PNL
Mr. Herb Meyer	Health Physicist	Mound / Retired
Dr. Jim Ruttener	Epidemiologist	Univ. Colorado
Dr. Steve Wing	Epidemiologist	Univ. N. Carolina
Dr. Ed Frome	Biostatistician	ORAU

The following sections represent highlights of each of the speakers' presentations and summary remarks from the other workshop attendants.

Historic Uses of Non-Detectable Data in Epidemiology: . Jim Rutenber

Dr. Rutenber opened the workshop with a review of how non-detectable values have been used in past epidemiologic studies. Four areas were covered :

- ① Classifications of Missing Dose Data in Epidemiology.
- ② Ways to Record Doses Below LOD.
- ③ Notional Dose Estimates Based on LOD.
- ④ Alternatives to Notional Doses.

Each topic is summarized in the following paragraphs.

Missing Dose Data:

Missing dose, censored, or non-detectable data have been encountered in past epidemiologic studies as a result of the following situations:

- Lost data.
- Strict monitoring criteria.
- Inadequate monitoring.
- Errors in monitoring.
- Exposure values recorded below the limit of detection.

Notional dose estimates are commonly used as surrogate exposure estimates when an abnormal event occurs such as an

invalid result, a lost dosimeter, or a worker's dosimeter cannot be processed. Notional doses are entries recorded in the exposure files as a quantity related to an administrative limit or minimum detectable reading (e.g., < LOD). This would tend to "left-censor" the dose distribution.

Doses Below the Limit of Detection:

Handling data which fall below the LOD is problematic and can lead to bias in the epidemiologic analysis. For example, if the portion of exposure data representing zeros is adjusted by setting the exposure equal to the LOD, then the cumulative dose would likely be overestimated, thus affecting the risk estimates calculated in the analysis. In addition to this method, other ways to utilize data below the LOD include: assigning some fixed number that falls between zero and the LOD, $LOD/\sqrt{2}$, assigning zero, using a notional estimate based on area monitoring data, or applying some alternative method based on the LOD as described below.

Notional Dose Estimates Based on the LOD:

At least three methods have been used in past epidemiologic studies to arrive at notional dose estimates based on the LOD. These include:

- ① $LOD / 2$.¹⁰
- ② $LOD / \sqrt{2}$.⁵
- ③ Maximum Likelihood estimation based upon assumption of a lognormal distribution of exposure measurements.¹¹

Alternative Methods for Handling Missed Dose, and Censored and Notional Data:

If the number of missed dose estimates and left-censored results is minimal, or if notional dose estimates are not desirable, other methods can be used to replace such data in epidemiologic analyses. One method would be to reconstruct exposure estimates from area air monitoring or direct radiation measurement data. This approach has several limitations which must be recognized and evaluated to determine its feasibility. Also, all associated assumptions and supporting information should be documented. For example, the purpose and scope of area monitoring must be determined and evaluated with regard to its intended use. The historical purposes for area sampling, e.g., compliance, hazard evaluation, control technology assessment, or safety alarm limits, inherently limits its utility to derive exposure estimates for epidemiology. Sampling duration, sensitivity, specificity, and purpose for sampling are all parameters for consideration. For example, short-term grab samples with a relatively high detection limit used to identify emission points in a process area may not be suitable for use in this regard. However using a measure of central tendency for integrated continuous area monitoring over several years with documentation on location of workers and time spent in the area may be very useable. This approach requires considerable expert judgement and documentation of the rationale.

Use of area monitoring data is most likely adaptable for assigning exposure estimates

to individuals or homogeneous groupings via a Job Exposure Matrix (JEM), defined below. Such assignment of exposure estimates requires identification of workplaces, work departments, and job titles over the history of the site. This task may be done in a unified way, with creation of a detailed multi-dimensional matrix incorporating information on standardized job titles, departmental assignments, building locations, process changes, work practices, and periods of work through time. Groupings of homogeneous exposure by job tasks, job titles, departments, or building location can be based on all available information, technical judgement, or statistical modeling of available exposure monitoring data. The dimensions of the matrix depend on the number of variables and the amount of information available in each variable.

Workshop Discussion: Epidemiologic Uses of Non-detectable Values; JEM

The discussion session following Dr. Rutenber's presentation focused on alternatives to notional doses. Considerable time was spent discussing the best way to use the actual recorded personal doses and area monitoring data in a manner that would not bias the epidemiologic outcomes, while taking into account the limitations of the historical data. The usefulness of developing a JEM dominated the session.

A JEM provides radiation exposure estimates for a group of workers based upon a common exposure experience.¹² Specific information on job titles, building or department codes and/or process tasks are examples of a common experience

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where a JEM may be applicable. The advantages of the JEM approach for epidemiology are:

- It is efficient to reconstruct average dose/exposure histories for each worker.
- It can supplement individual radiation dose/exposure records whenever gaps or censoring have been identified.

Reconstruction of exposure histories based on a common experience avoids the need to evaluate individual occupational dose histories for each worker, thus making efficient use of available resources. The JEM can also be used to supplement individual radiation exposure estimates whenever gaps or censoring have been identified. Unfortunately, throughout the history of the DOE facilities, workers regularly changed jobs and work locations without a change in job classification or title. Likewise, records of job title changes may not be truly reflective of the actual working conditions, since it was believed that specific job activities could provide information about the secret nature of work being conducted at the DOE facilities. Therefore, job titles and descriptions were intentionally vague to avoid the risk of releasing any information that might be construed as a breach of security. These practices make the JEM more difficult to develop for epidemiologic use.

Limitations in applying the JEM approach to epidemiologic studies at DOE facilities are:

- Monitoring programs were implemented to assure efficiency of

engineering control systems, not to estimate exposures.

- Many technological changes were being implemented, affecting the accuracy of the monitoring measurements.

Historically, air sampling programs were not conducted to estimate worker exposures but to check the operation of engineering control systems, such as glove boxes and other containment systems. Therefore, many sampling locations were placed in areas where abnormal conditions would most likely occur. Usually these locations were not representative of the workers environment. In addition, the location of samplers, the duration of samples, airflow rates and sampling frequency were not optimal for estimating worker exposures. The measurement itself was designed for a qualitative rather than a quantitative indication of exposure. Also, the specificity (knowing which radionuclide was being measured) was not a monitoring requirement.

During the 1940s and 1950s, significant improvements in technology were being implemented for both the personal and the area monitoring programs. If a JEM were to be developed using these data, certain assumptions have to be made along with a careful review of the production processes and their related jobs.

Once developed, the matrix is used to assign exposure estimates for agents of interest. At DOE facilities the JEM approach would be most useful for estimating exposure to chemical agents and perhaps internal radiation exposure. Enough individual measurements generally exist for external whole-body radiation to

make the JEM approach unnecessary. In all likelihood, the exposure monitoring data used to derive exposure estimates for the cells of the matrix will involve real measurements (with an attributable variation or uncertainty) plus missed dose, left-censored and/or notional data. The data used for each cell must be evaluated for the proportional contribution of each data type and a decision made regarding the influence on the estimate. For example, in a cell of a given matrix, 36 measurements are available for use to derive an exposure estimate for the job title Decontamination Technician, within the Chemical Processing Department, in Building 379, for the year 1964. Of the 36 measurements, 6 are reported as non-detectable and would require one of the previously described imputation strategies to assign a number for each in order to calculate a mean for the 36 data points. This may be accomplished by examining the distribution of the values in the data set, or by assigning a number for each censored data point using $LOD/2$ or $LOD/\sqrt{2}$. In some cases the amount of non-detectable data used in deriving an estimate for a cell will be minimal and would not lead to misclassification of exposure. In other cases, the available data may require augmentation from additional data sources, e.g., other area or personnel monitoring data, to derive a reasonable and defensible estimate.

Subsequent exposure monitoring may be utilized to increase existing information, derive an exposure assignment to fill an empty cell, validate the historical monitoring data used, or to enhance the basis for a derived estimate. This approach should only be applied in

situations where process operations and exposure potentials have not substantially changed over time. This approach may be extremely beneficial where parameters of increased sensitivity (lower detection limit), improved specificity (reduced interference), and accuracy of analytical procedures are evident. With external monitoring there was generally an improvement in these parameters when the period for wearing dosimeters was increased.

Exposure assignment may be categorical or quantitative in approach depending upon the type, quality, and quantity of data used to create the matrix. Exposure assignment may:

- ① be defined as "ever" versus "never" exposed;
- ② be based on duration of exposure or employment in a job title, department, building location, i.e., categories such as high, medium, low;
- ③ consist of a semi-quantitative estimate of exposure for broad work categories based on analysis of exposure monitoring and process data; or,
- ④ represent a quantitative estimate of exposure for narrowly defined work groupings based on detailed high-quality exposure monitoring and process information.

A matrix may be constructed using one of these exposure assignments depending on the quality and quantity of information used. When feasible and appropriate, a subset of data may be held in reserve and used to test the validity of an exposure assignment. Additionally, an expert panel

could be convened to review and evaluate the validity of exposure assignments.

Historic Overview of External Monitoring Methods: *Herb Meyer*

Mr. Meyer, former manager of Health Physics for Monsanto Research Corporation at the DOE Mound Plant, described the historical DOE external dosimetry program involving the use of pocket ion chambers and film dosimeters as the methods for monitoring external radiation exposure. Neutron dosimetry using film badges is also discussed. Finally, the discussion session summarizes contributions from members of the meeting who provided additional insight to the historical external dosimetry practices at the DOE.

Pocket Ion Chamber (PIC):

A pocket ion chamber, see Figure 1, is essentially a capacitor which holds about 150 volts. Photon interactions in the wall of the PIC discharge the capacitor. The amount of discharge is related to the exposure received by the individual. PICs were used as the official record of external exposures to ionizing radiation until about 1944, when Hanford Engineering Works made film badges the official record.¹³ Prior to 1944, they were routinely (daily) used to assure a workers exposure was within the radiological limits.

Advantages:

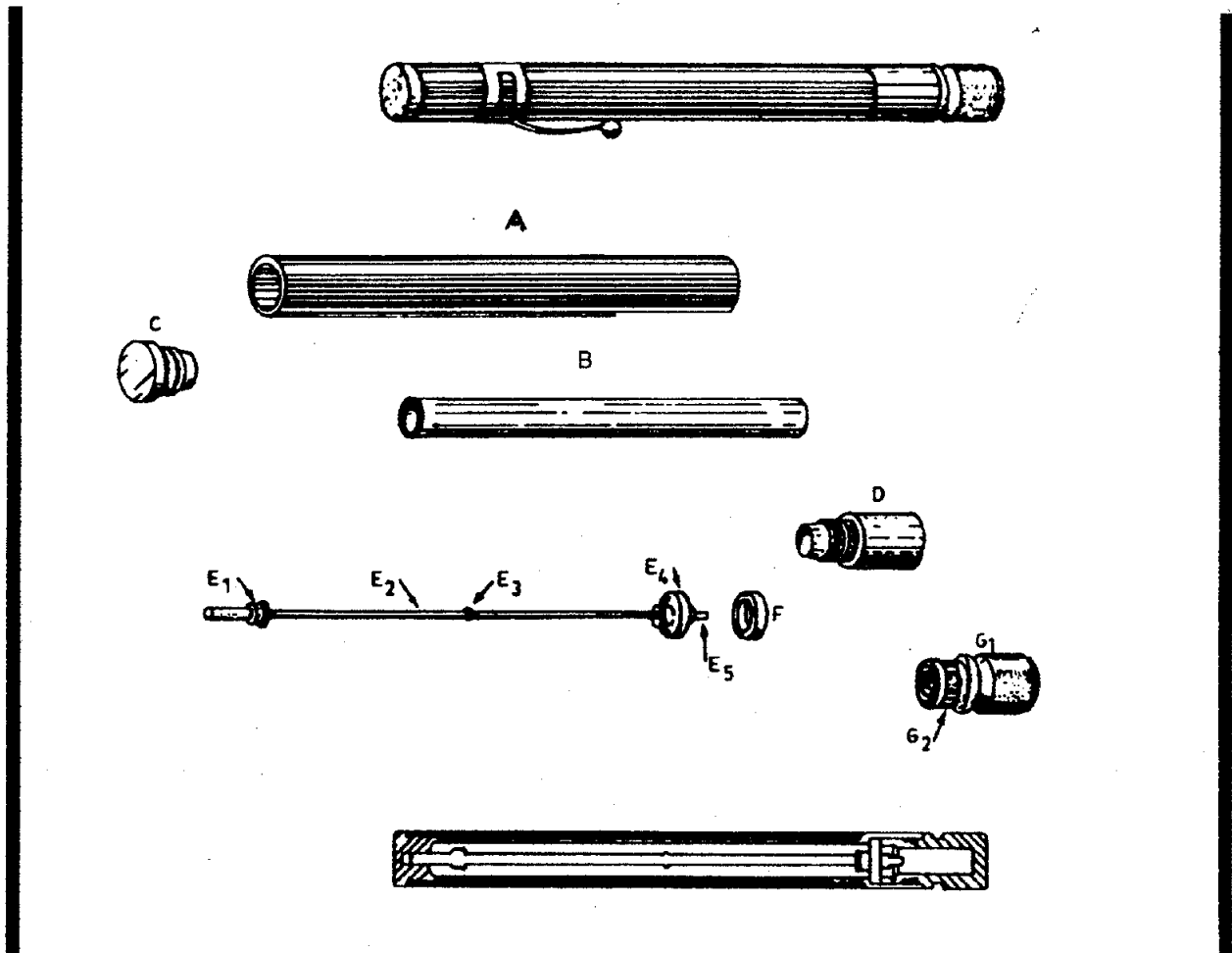
Although PICs proved to be a useful instrument for compliance purposes, their usefulness for epidemiologic studies is

still to be determined. Several "epidemiologic" advantages for using PIC exposure data are:

- PIC data provide individual exposure information.
- Frequent monitoring results are available (often daily).
- Lower limit of detection than film badges
- PIC exposure data exist in historical documents.

Having individual exposure data is ideal for conducting epidemiologic studies, and the PIC data provide this type of information. Daily monitoring of the workers' activities is also very useful, especially in the exposure assessment portion of a study. For example, combining an individual's exposure history with his work activities/responsibilities can help estimate a co-worker's exposure that is missing. PIC data also provide critical information that may be used to build a JEM for a group exposure. Another advantage is that the PICs have lower LODs (about 0.02 mSv) than the film badge (about 0.3 mSv) and is easier to read at the lower ranges. Historically, during read-out the spacing between numbers was further apart at the lower exposures and was closer together at the higher exposures, making the lower exposures easier to read. Finally, historical PIC records exist at these facilities and can be utilized for future studies. However, the magnitude of this type of task could be quite large and expensive. Its important to consider the cost effectiveness before taking any steps to improving the exposure data.

Figure 1
Pocket Ion Chamber



- A. Low Atomic Number Wall
- B. Graphite-Coated Paper Shell
- C. Aluminum Terminal Head
- D. Aluminum Terminal Sleeve
- E₁. Polystyrene Support Bushing
- E₂. Central Electrode, Graphite Coated

- E₃. Polyethylene Insulating Washer
- E₄. Polystyrene Fixed Bushing
- E₅. Electrode Contact
- F. Retaining Ring
- G₁. Aluminum Base Cap
- G₂. Polyethylene Friction Bushing

Limitations:

Use of PIC data in epidemiology must be carefully evaluated because of the following limitations:

- PICs can only measure gamma and "hard" betas, (specificity).
- Physical sensitivity; and
- Frequent false-positive readings.

The first limitation introduces a potential problem for epidemiology if a site has processes where neutrons or "soft" betas are present. X-rays or gammas between 40 keV and 1 MeV and "hard" betas above 1 MeV are measured with an accuracy +/-15%. Specially, designed PICs with boron impregnated within the chamber may have been used for neutron detection, but were not discussed. The limited energy range of these instruments could cause the cumulative external exposures to be underestimated. In addition, their energy dependence, which has not been studied, could be a bias in the exposure assessment.

Another limitation of the PIC is its physical sensitivity. A discharge (or high reading) can be induced by physical shock, such as dropping the PIC, excessive humidity, or dirt on the electrical connections. Physical design characteristics allow the PICs to potentially produce false-positive readings but *never* a false-negative reading. Thus, they were issued to workers in pairs and the lower of the two readings was recorded as the official exposure. The higher reading would be considered a false positive due to "leakage" or some other physical deficiency. If false-positives are incorrectly used in the cumulative estimate, an overestimate of the exposure would occur. The effects of energy dependence and false-positives may negate their overall bias' in an epidemiologic study. However, this has not been studied.

Film Badge Dosimeters:

The early dosimeters used at DOE facilities, see Figure 2, were adopted from those developed at Oak Ridge, Los

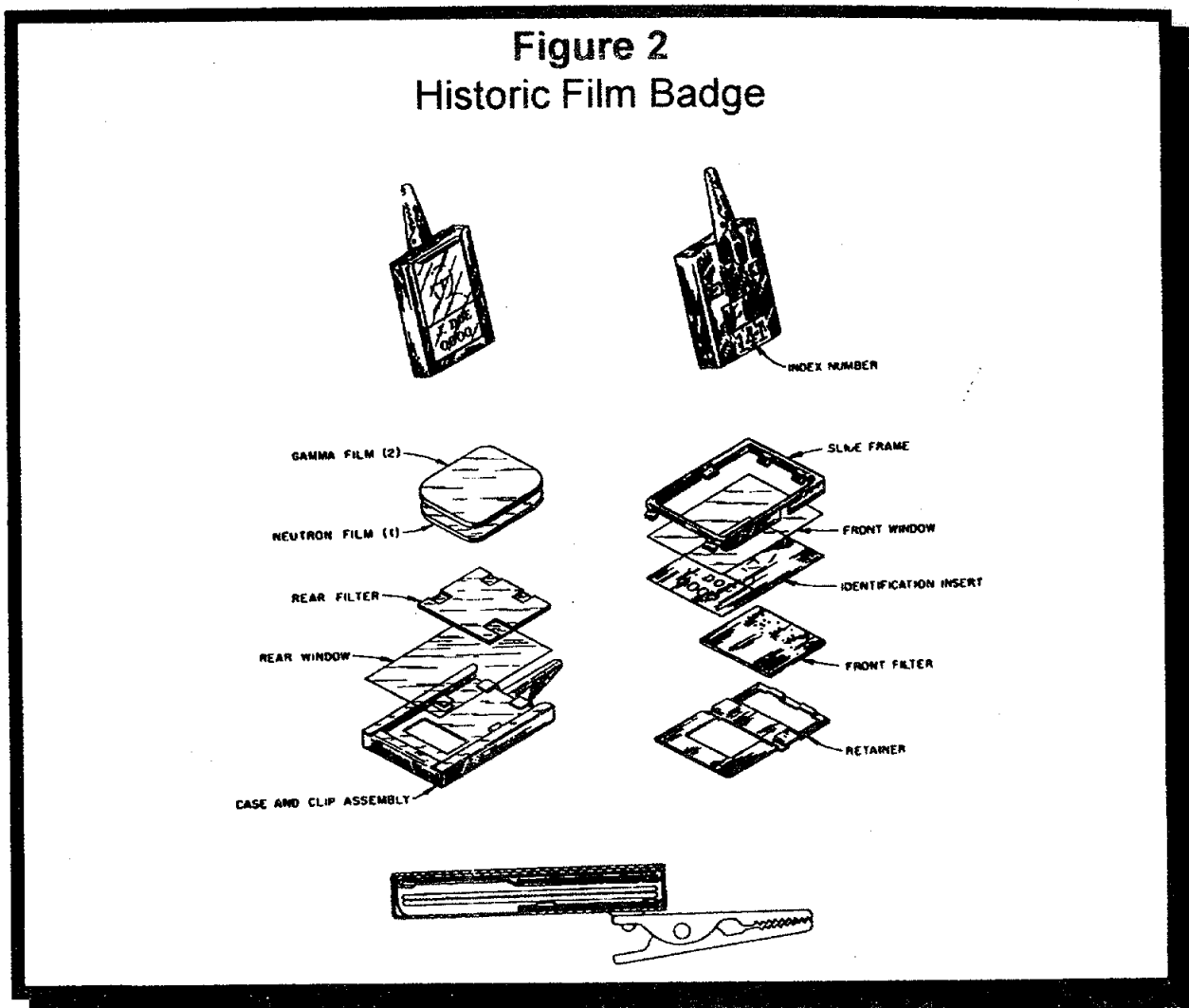
Alamos, and Hanford, since the measurement technology was developed in cooperation with these facilities in the early history of the Manhattan Project. The lead laboratory in the design of the film dosimeter was the University of Chicago as described in report CH-1553 dated 4/8/1944.

Each DOE facility modified the original design of the film dosimeter to suit their individual needs because radiation fields and radioactive materials encountered at each site were unique. The first personnel radiation dosimeters used on a routine basis consisted of at least one piece of duPont type 502 and/or 510 x-ray photographic film plus a set of absorbers or shields to help characterize the radiation. The absorbers included several different types of metals including cadmium, lead, brass, and tin. Areas behind these absorbers are commonly referred to as the "closed window" or "deep" doses. The film dosimeter casing was also designed so that a portion of the film would have no absorber, referred to as an "open window" or "shallow" dose, detecting primarily beta particles. The resulting beta and gamma exposures were determined by an algorithm that was developed from the calibration procedure.

Special case - neutron dosimetry:

Nuclear Track Emulsion (NTA) films were used for neutron dosimetry starting in the late 1940s. Although the film was processed in a manner similar to that for the gamma radiation dosimeter, neutron tracks rather than film darkening were measured. The weekly "tolerance limit" for neutron exposure was 150

Figure 2
Historic Film Badge



neutrons/cm²-sec which is equivalent to approximately 300 mrep (roentgen equivalent physical). Eventually, the weekly tolerance limit was reduced in stages to 30 neutrons/cm²-sec in 1956. Unfortunately, historical occupational radiation exposure records at several DOE facilities recorded the neutron dose as a multiple of the tolerance limit, making a dose adjustment more difficult. Exposure assessment strategies must take into account these factors to assign appropriate dose estimates for epidemiologic studies.

Advantages:

Beginning as early as 1944, doses determined from film badges became the official record for compliance reporting, replacing the PICs. Therefore, most of the historical exposure data used in epidemiology today is in this form. The advantages of using film badge data in epidemiologic studies are:

- Individual exposure information.

- Permanent record which could be re-read if available.
- Measures a wider range of photon and beta energies than PICs.
- Measure neutrons with greater accuracy than PICs.
- Less susceptible to interpretational error than PICs.

Film badges, like PICs, also provide individual specific exposure information. A major advantage of the film badge is the ability to go into the archived records and re-read a sample of the old film badge results. This permanent record of dose allows historical data to be verified and checked for accuracy. This option has its limitations though, available historical calibration curves, adverse storage conditions, poor film integrity, and fading of the films all pose significant problems to successfully re-reading old film badges.^{14,15}

There are other options that can be considered prior to re-reading all the badges. One would be to obtain an important piece of information that must be included with the original film, the data processing sheets. These data sheets show the optical density observed with each personnel film along with the associated calibration results. If these records are available, it would be much simpler to review these for accuracy than attempting to re-read the original film.

Other advantages of the film badges are a wider response to photon, beta and neutron energies and they are less susceptible to interpretational error, resulting in a truer measure of external exposure than the PICs.

Limitations:

While film badge results make up the majority of historical external dosimetry information used in epidemiology, several limitations need to be considered prior to applying the data to an epidemiologic analysis:

- Higher limit of detection (around 0.30 mSv).
- More results fall below the LOD with higher sampling frequency.
- Responses at low energies (< 100 keV) were exaggerated.
- Units of measurement have changed.
- Training and intensive work are required to determine neutron exposures.

The film badge typically had a LOD of about 0.2 to 0.4 mSv (20-40 mrem) compared to about 0.02 mSv (2 mrem) for the PIC. Historically, some records show recorded external dose from a film badge as low as 0.1 mSv (10 mrem), but these values are considered highly uncertain by the site health physicists.¹⁶ A 0.2 mSv LOD would not pose a significant problem as long as the exposure time was significantly long enough to have received at least 0.2 mSv. However, this was often not the case at these DOE facilities. The frequency of dosimeter change out occurred on a weekly, monthly, quarterly, or sometimes on a semi-annual basis. Weekly change outs occurred most often in the earlier years creating the greatest potential for a missed dose. The missed dose concept will be addressed later in this paper. However, it is important to note that this concept can adversely affect epidemiologic evaluations for calculating

risk factors because the cumulative exposure estimates are underestimated. Knowledge about frequency change out is important for a proper exposure assessment.

Another limitation of the earlier film badges is the sensitivity to photon energies below 100 keV. Facilities that processed radionuclides that decayed with photon energies below 100 keV are likely to have higher than true exposure results. Knowledge about dosimetry algorithms used at that time could determine if the over response was accounted for in the record.

Reporting units of the film badge doses changed over time. The original unit of measure was the roentgen, an exposure unit not a dose unit. The dose unit was the rep, roentgen equivalent physical which, for most photon energies, was equal to the roentgen. Later, the rep became the rem, roentgen equivalent man. Historical dosimetry data reported in different units must be converted to a common unit prior to the epidemiologic analysis. This limitation is of particular importance, especially in estimating a dose due to neutron exposures, in which the conversion from roentgen to rem is not equivocal.

Neutron dosimetry introduces other limitations because different procedures are used to determine a person's dose. An intense effort is required by a trained technician to count microscopic tracks created by a re-coiled proton particle in the film. Depending on the initial neutron energy, some tracks are easier to identify than others. Limitations associated with neutron dosimetry include: labor intensive

work, the need for highly trained technicians, and fading of up to 30% of the original reading may occur during storage. Most of these limitations can be taken into account today by advanced computer software packages and programs.

Workshop Discussion: External Dosimetry Issues

Additional contributions were provided by Dan Strom, Jack Fix, Hap West, and Bill Tankersley based upon their experience and research dealing with PICs and film dosimeters. The main focus of their discussion was directed at developing recommendations for evaluating external dosimetry data recorded as zero, censored, missing, or shown with a notation such as <LOD. Dan Strom provided a list of papers and reports that specifically address the issues covered in this workshop (Appendix A). Bill Tankersley presented material on an approach for supplementing missing or censored film dosimeter data with measurements from PICs.¹⁷

Biases:

Several sources of bias were identified as a result of this discussion, such as assignment of zero dose whenever results were missing or unusual. Other practices were less extreme, such as interpolating lost results or assignment of the dose from a co-worker when an individual's results were lost or questionable. Average doses for a department or plant have also been assigned to workers in an attempt to replace lost or missing measurements. A more complete discussion on the general issue of uncertainty in individual dose estimates in epidemiologic studies of

nuclear workers is presented in several references.^{4,18,19,20}

Missed Dose Concept:

The missed dose concept was introduced as another source of bias. The degree to which the limited sensitivity of a dosimeter can increase the dose missed depends on the frequency with which it was exchanged. To illustrate this trait, assume that the sensitivity (LOD) of each dosimeter worn by a worker was 0.2 mSv (20 mrem) and that this was the worker's average dose during the monitoring period. If that dose was reported as being below the LOD, then a monthly badge exchange would introduce an effective detection threshold of 2.4 mSv/yr (240 mrem/yr). This assumes that the dosimeter reading is recorded as zero or <0.2 mSv every month. If it was recorded as <0.2 mSv fifty percent of the time and 0.2 mSv the remaining fifty percent, then the resulting effective detection threshold would be 1.2 mSv/yr (120 mrem/yr). Similarly, the impact of a missed dose could be greater for a weekly exchange period, a common practice throughout the DOE complex during the 1940s and early 1950s, resulting in a potential missed dose equal to 10 mSv/yr (0.2 mSv per week x 50 working weeks per year) or 5 mSv/yr assuming fifty percent probability.

Another factor making the missed dose concept a significant problem is the lack of quantitative information on the precision and accuracy of routine calibrations. Detection limits are often quoted between 0.2 to 0.4 mSv (20 - 40 mrem) but may not reflect the actual performance of the detector corrected for background.

Jack Fix noted in a post-workshop letter that:

"An important re-occurring concept of the workshop discussion is the significance of the LOD, of about 0.3 mSv, for the individual film results. For example, there is discussion of the potential annual missed dose if film dosimeters are exchanged weekly. However, I believe this topic is much more complicated. Personnel dose is typically calculated from the difference between the response of personnel film and the response of the background film. There is variability in both of these quantities, likely about 0.1 mSv. As such, the true question is the significance of the differences between personnel and background film, each with a detection level of about 0.3 mSv and a variability of about 0.1 mSv. For truly background data, the case can be made that too much dose will be recorded. Another perspective is the true detection level for cases where all reported values are zero for the same individual in the same work environment. The actual non-truncated values can be represented by a distribution of values. Assuming the detection level is 0.3 mSv and there are 50 independent observations, then a maximum of 1% of the area of the distribution would lie above 0.3 mSv for a normal distribution. In fact, the area will be less than 1% if the skewness of the distribution for low dose results is considered. This entire area involves several complex issues. Likely only actual near-zero laboratory data can resolve these issues with confidence."

Historic Overview of Internal Monitoring Methods: *Bill Moss*

Mr. Moss presented information on the methods used to determine internal doses from plutonium exposures. The evolution of plutonium radiochemistry procedures, LODs, and potential problems in the dosimetry records were summarized. Due to time constraints and the nature of the material presented, it was decided that a detailed discussion on internal radiation doses and their applicability to epidemiology should be tabled for a future workshop. However, several problems with the dosimetry data were mentioned in his presentation which could have an effect in a risk assessment. Specific limitations mentioned include: residual material contaminating laboratory equipment causing a false-positive, difficulties in obtaining 24 hour fecal and/or urine samples, computer modelling limitations, biokinetic variations, lag time in analyses, chronic vs. acute intake determinations, and parent to decay product relationships within the body and determining organ doses.

Detection Limit Quandary and Missed Dose Concepts: *Allen Brodsky*

Dr. Brodsky presented data and information related to the problem of estimating radiation doses of populations under study for radiation risk assessment. Particular emphasis was placed on that portion of the population whose radiation doses were below the limit of detection or

were biased in some other manner. Topics in his presentation included:

- ① Resources useful in defining LODs
- ② Sources and magnitudes of errors in dosimetry.

A brief summary of his presentation follows, additional information is available in the references.

Resources useful in defining limits of detection:

Historical definitions for detection capability varied considerably from site to site. For example, various formulas used were two times background or two or three times the standard deviation of the blank. The Health Physics Society (HPS) organized a working group to review the literature on the statistical basis of detection limits. Their recommendations were based mainly on Currie's work.^{21,22} NUREG-1156 describes how the concepts of LOD can be applied to measurements other than the counting process and discusses the concepts of bias and precision.²³

Sources and magnitudes of errors in dosimetry:

A personnel dosimeter yields a point estimate of exposure at the position of the dosimeter on the worker, not a whole body exposure. If a dosimeter result was below a "subjective impression of a detectable amount" (or a minimum detectable dose), a zero dose would be recorded. Alternatively, a more conservative approach is to assign a dose equal to the LOD to ensure that the worker's

cumulative dose would not exceed the regulatory limits. This was illustrated earlier in "Dose Below the Limit of Detection." However, even these practices changed over time and from site to site.

Dr. Brodsky also described relevant sources of uncertainty in both the measurement and in the conversion of the measurement result to dose. Estimating the uncertainty associated with missed doses or the bias in dose estimates requires knowledge of errors, error distributions, and the statistical characteristics of the underlying exposure distributions. In addition, he described the energy response characteristics of film dosimeters and some of the improvements in densitometry during the 1960s. Density calibration curves for different types of film and dosimeters were also described including the variance observed in intercomparison measurements. The influence of temperature and relative humidity on the cumulative quarterly dose assigned to film dosimeters that were exchanged at different frequencies does not limit the precision of the weekly films, except for high temperature/high humidity conditions under which many films were lost.¹⁵

In summary, Dr. Brodsky showed that many populations have lognormal exposure distributions repeatedly, year after year. The average exposures, or population exposures, of low-dose portions of monitored populations can often be assessed assuming that the shape of the exposure distribution is lognormal below an annual dose of 10 mSv (1 rem). A cumulative plot of the exposure data can usually be fitted by a straight line in the region from 1 to 10 mSv (0.1 to 1.0 rem),

which can then be extrapolated to lower exposure regions for assessing the average doses. This analysis can be applied to portions of the population or to the total population for doses below about 1 mSv (0.1 rem).²⁴

External Exposures at ORNL and Their Implications for Epidemiology:
Steve Wing

Dr. Wing recommended evaluating the distribution of doses recorded over time and expressed the critical need to have accurate radiation exposure data on individuals to properly assess radiation-mortality associations. He discussed changes in recorded doses and in radiation monitoring programs at Oak Ridge National Laboratory. Numerous changes in monitoring programs occurred between 1943 and 1984, including the types of dosimeters used, the frequency of reading dosimeters, methods of calculating doses, and practices of recording doses. Temporal patterns of doses in the lower range of the distribution suggest changes in policies and practices for recording doses. These changes could influence dose values used in epidemiological studies. Reliable and accurate exposure measurements are especially important in studies of low level exposures due to small differences in outcomes between exposure groups. Changes in recorded doses due to monitoring and recording practices emphasize the need for comparable epidemiological studies of radiation mortality associations in other populations.²⁵

**One Solution/Approach Used on a
Oak Ridge Cohort: *Edward Frome***

Ed Frome from ORNL and several representatives of ORISE (Bill Tankersley, Janice Watkins, Hap West) described an approach used to adjust cumulative dose estimates at the facility in Oak Ridge. They determined that the general practice at ORNL between 1944 and 1956, was to read badges on a weekly basis.²⁶ Results below the limit of detection (about 0.3 mSv during this period) were recorded as zero. They assumed that some of the annual recorded zeros actually represented true zero exposures above background, while others were an underestimate of true low-level positive doses. They identified true zeros by the following criteria:

- ① Workers employed for five or more years with all zero readings.

and

- ② The department in which a person worked most frequently had 75% or more zero readings.

All the other annual readings were adjusted upward by an algorithm developed from a sample of several hundred hard copy records which contained both film badge and pocket meter readings. For each week that the shielded film badge was recorded as zero but where weekly pocket meter readings were available, the pocket meter readings were summed to estimate the dose missed by badges during the year. A least squares regression was applied to these data to develop a prediction equation for the amount of upward adjustment as a function of the unadjusted annual recorded doses for all workers with recorded annual

doses below 16 mSv. All workers above 16 mSv were given an extra 3 mSv. Use of this algorithm resulted in a mean increase of approximately 5 mSv per year before 1956. Additional details of this approach are provided in a technical report.¹⁷

Dr. Frome suggested an alternative approach to account for both uncertainty and bias in the dose measurement.²⁷ The estimated dose could be treated as a probability distribution developed from all the historical data recorded for an individual during the year. This method based upon Bayesian statistics requires knowledge and/or assumptions regarding the true performance of the dosimeter. Complicating the development of these probability distributions with time are the same problems encountered with other methods of retrospective dose assessment: the changes in dose measurement techniques, dosimetry monitoring programs, and recording practices. In order to estimate the true distribution of doses over a period of time (known as the prior distribution in Bayesian analysis) weekly pocket meter readings were used. This approach results in an adjusted dose distribution for a specified period of time that can be used to reassign person-years in an epidemiologic study to the adjusted dose intervals. Frome concluded that the adjusted dose distributions were almost always centered above the recorded dose distributions. In some cases there was severe underestimation of true dose using the recorded data. The degree of underestimation was proportional to the number of recorded zero weekly film badge readings. This approach is considerably more complex than the

approach used by ORISE, but has the advantage of addressing problems in both bias and uncertainty (precision) rather than bias alone.

Workshop Discussion: Use of PIC Data in Epidemiology

After their presentation, a workshop discussion attempted to resolve the question pertaining to use of the PIC as a supplement to the film dosimeter result. The approach that was described focused on the Oak Ridge National Lab cohort between the time periods where PICs and film badges were worn side by side. Records for the daily PIC results were compared with weekly results for the film dosimeter. One option for using PIC data is when a zero dose (or notional dose) recorded for the weekly film result is reported. Film results could be replaced by summing the daily results obtained from the PIC. However, this task required extensive data entry and increased cost to improve the ORNL data.

An alternative recommendation was made to evaluate the open and closed window results from the film badge to confirm that the dose was truly a zero. A recorded non-penetrating or shallow dose based on the response of the open window component of the film dosimeter can be an additional important source of information to ascertain the significance of deep dose nondetectable results. An open window dose has no absorbers, allowing all radiation to expose the film. Therefore, the open window portion of the film would always have a positive reading if any exposure occurred. A truly zero dose occurs when

the open window dose on a film badge is read as zero exposure.

Recommendations were made for using daily PIC data to supplement weekly film badge results if the closed window dose (deep dose) estimates have been recorded as zero. This method is similar to that proposed for use at the Oak Ridge National Lab to alleviate data censoring. The combination of PIC data and film results could be used if historical data censoring was found to be a problem.

A matrix was developed during the workshop discussion session, which describes the logic for using PIC data in an exposure assessment. This matrix was suggested as a method to validate the true zero doses recorded from the film dosimeters by interpreting the open window and closed window results. The sum of daily PIC results to supplement the weekly film dosimeter result whenever:

- ① The film dosimeter open window dose was greater than zero (suggesting some low energy exposure) but the penetrating dose was recorded as zero.

or

- ② To validate positive film dosimeter results using PIC data.

Case (1) was adopted in recognition of the sensitivity of the open window portion of the film dosimeter in detecting both beta particles and low energy photons. Since it is not known when such exposures were received, a conservative approach is taken to report the result from the adjusted dose equation as the true dose that will be used in the epidemiologic analysis. This requires documentation on the calibration

procedure. If this documentation is not available, then the adjusted dose should represent the sum of the PIC results. Case (2) was adopted to be consistent with case (1) such that the PIC results could be incorporated to confirmed positive weekly results.

The matrix also indicates that any film dosimeter result having an open window dose equal to zero but showing a positive closed window result is highly suspicious since the open window portion of the film would have to show at least the same exposure as the closed window portion of the film. This feature would be applicable to all facilities using the film dosimeter since all designs included the open/closed windows to differentiate beta and low energy x-ray exposure from high energy photons. Therefore, site specific data should be obtained on the dosimetry program to support the retrospective interpretation of the films.

Matrix for Supplementing Film Badge with PIC readings

CLOSED WINDOW film result

	0	>0
OPEN WINDOW film result	0	true zero invalid film or true zero
	>0	see equation below Case (1) Use Film Result

$$\text{ADJUSTED DOSE} = \frac{\sum(\text{PICs}) + \text{Open Window}}{2}$$

exposures on a site-by-site basis. Where appropriate, the data could then be combined for working populations across the sites rather than start with a qualitative approach.

An alternative recommendation was made that exposures across the DOE facilities could be compared if site-specific, annual mean doses were determined. Since epidemiologic studies often divide exposed workers into groups based upon dose (exposure), it may be possible to compare worker cohort groups. It was concluded that individual doses were desirable whenever possible since the mean is not an adequate descriptor of exposure variation. Therefore, the uncertainty in the dose estimates should be determined since the objective of the epidemiologic study is to determine the risk per unit of dose. The workshop members agreed, in principle, that exposure assessments would have to be conducted on a site by site basis. This would allow individual problems at each site (especially those related to internal

Recommendations

A recommendation to combine populations across the DOE complex was considered premature because each site has unique dosimetry problems that have to be resolved before the data could be considered comparable. It was agreed that the ultimate goal should be to quantify

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dose) to be addressed so that future study of working populations across several sites can be accomplished.

Future Workshops:

Topics for future "Research Issues Workshops" are listed below:

- Issues relating to internal dosimetry and its application to epidemiology.
- Issues regarding energy level and geometry factors, organ dose from both internal and external exposures, developing estimates of uncertainties and identifying biases encountered in dosimetry and risk estimation.
- Issues related to the identification and collection of historical records for use in these studies.
- Issues related to the effects of chemical exposures.

APPENDIX A

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Compiled by DJ Strom and HR Pritchard, rev. July 28, 1992

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