Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Summary Minutes

Advisory Board on Radiation and Worker Health's Meeting of the Subcommittee for Dose Reconstruction and Site Profile Reviews

August 23, 2004

Meeting held at the Shilo Inn Suites
Idaho Falls, Idaho

NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

Summary Minutes of the First Subcommittee Meeting

August 23, 2004

The First Meeting of the Subcommittee for Dose Reconstruction and Site Profile Reviews (the Subcommittee) for the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Shilo Inn Suites on Monday, August 23, 2004. The Meeting was called by the Centers for Disease Control and Prevention's (CDC's) National Institute for Occupational Safety and Health (NIOSH), the agency charged with administering the ABRWH. These summary minutes are available on the internet on the NIOSH/Office of Compensation Analysis and Support (OCAS) web site located at www.cdc.gov/niosh/ocas. Those present include the following:

ABRWH's Subcommittee for Dose Reconstruction and Site Profile Reviews Members:

Dr. Paul Ziemer, Chair; Dr. Henry Anderson; Dr. Antonio Andrade; Mr. Michael Gibson, and Mr. Mark Griffon.

Designated Federal Official: Mr. Larry Elliott, Executive Secretary.

NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

Federal Agency Attendees:

Department of Health and Human Services:

Mr. Todd Braswell, Ms. Chia Chia Chang, Ms. Heidi Deep, Ms. Chris Ellison, Mr. Russ Henshaw, Ms. Cori Homer, Ms. Liz Homoki-Titus, Mr. Ted Katz, and Dr. Jim Neton.

Department of Labor:

Mr. Pete Turcic

Contractors: Dr. John Mauro

National Council on Radiation Protection and Measurements: Dr. Thomas Tenforde and Ms. Melanie Heister

Public Attendees: Louis Z. Bodnar, H. Dale Egbert, and Gaylon Hanson

NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

Executive Summary

The First Meeting of the Subcommittee for Dose Reconstruction and Site Profile Reviews (the Subcommittee) for the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at the Shilo Inn Suites on Monday, August 23, 2004. All appointed ABRWH Subcommittee members attended. Other individuals in attendance included staff from various Federal agencies, as well as members of the public.

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Monday, August 23, 2004

Subcommittee Working Session

Two documents relative to case selection procedures were provided to the Subcommittee for review and development of recommendations to the Board.

A sampling scheme and two sets of case selections, as developed at a prior working group session, were presented to the Subcommittee for review, comment, and discussion toward finalizing recommendations to the Board.

The Subcommittee made modifications to the case selection documents and recommendations were established to move forward to the Board.

A discussion ensued regarding the best procedures for assigning board members to work with Sanford Cohen & Associates (SC&A), case review processes, and panels serving for case review while addressing conflict of interest and Privacy Act information controls.

SC&A proposed a plan for the case review process involving the Subcommittee, the Board, and NIOSH.

Discussion was initiated on the nature and character of the final product for the Board's recommendations to the Secretary of HHS and to the Director of NIOSH.

With no further business to come before the Subcommittee, the meeting was adjourned.

End of Executive Summary

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NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

The Subcommittee for Dose Reconstruction and Site Profile Reviews

Advisory Board on Radiation and Worker Health

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention

Summary Minutes of the First Meeting

August 23, 2004

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NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

ABRWH Subcommittee for Dose Reconstruction and Site Profile Review Members:

Dr. Paul Ziemer, Chair; Dr. Henry Anderson; Dr. Antonio Andrade; Mr. Michael Gibson, and Mr. Mark Griffon.

Designated Federal Official: Mr. Larry Elliott, Executive Secretary.

Federal Agency Attendees:

Department of Health and Human Services:

Mr. Todd Braswell, Ms. Chia Chia Chang, Ms. Heidi Deep, Ms. Chris Ellison, Mr. Russ Henshaw, Ms. Cori Homer, Ms. Liz Homoki-Titus, Mr. Ted Katz, and Dr. Jim Neton.

Department of Labor:

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Dr. Paul Ziemer called the meeting to order at 9:00 am, welcoming the attendees. He remarked that the Subcommittee has specific functions, which are found in the charter, and the Subcommittee will be pursuing those duties and responsibilities. He asked everyone to register his or her attendance. He announced that the Subcommittee session does not have a public comment period, as it is an opportunity for the public to observe the Subcommittee at work. **Dr. Ziemer** noted that staff members are in attendance to serve as resources for the Subcommittee.

Mr. Larry Elliott introduced Ms. Heidi Deep, the writer/editor for the day's Subcommittee meeting. He announced that Ms. Deep is an ASPH Fellow recently assigned to OCAS and that will be serving as a Health Communications Specialist on Ms. Chris Ellison's team.

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SUBCOMMITTEE WORKING SESSION

Dr. Ziemer remarked that the purpose of the Subcommittee meeting is to develop a set of recommendations to bring to the Board regarding the selection of cases to be audited, the process of review, and the audit criteria documents. Subcommittee members received the following documents prior to the day's Subcommittee meeting: (1) A Draft Procedure for Selecting and Tracking Dose Reconstruction Cases; (2) Table 1 Flow Diagram of Case

Selection Procedure (also referred to as the Flow Diagram), both developed by a prior working group; and (3) two sets of case selections, as requested by the working group and developed by a team at NIOSH-OCAS. (Documents in (1) and (2) are attached for the reader's information. Documents in (3) are not attached, as they were working documents of the Subcommittee.) Previous discussion regarding methods of case selection included pure random sampling versus stratified random sampling with conditions to satisfy the matrix. **Dr. Ziemer** called upon **Mr. Mark Griffon** to explain the proposed Draft Procedure for Selecting and Tracking Dose Reconstruction Cases and the Flow Diagram of Case Selection Procedure.

Mr. Griffon explained the Flow Diagram of Case Selection Procedure as a case selection method geared to fill a matrix with parameters that will represent the cross-section of cases that have gone through the dose reconstruction and compensation process. Initiating the Flow Diagram of Case Selection Procedure is a random selection process or a random number generator used to select cases out of the list of available or completed dose reconstructions. Once the cases are randomly selected, the probability of causation (POC) for each case is distributed into one of three groups: (1) 0 - 44.9%, (2) 45 - 49.9%, or (3) greater than 50%. **Mr. Griffon** indicated that more emphasis would be placed on the borderline cases, in terms of POC, and then defined the proposed percentages for each group. **Mr. Griffon** pointed out the descending parameters in the Flow Diagram of Case Selection Procedure is considered of most interest in terms of a good cross-section of cases. The

remaining parameters were described and include (1) decade first employed, (2) duration of employment, and (3) cancer risk model. Other parameters of interest to the Subcommittee that will be recommended to the Board for tracking and monitoring are noted in a box at the bottom of the document (see Flow Diagram of Case Selection Procedure) and include: cases using co-worker data, monitored or unmonitored workers, job categories, work area or building, and primarily internal dose or external dose contributing to overall dose. **Mr. Griffon** added the other factor to deliver to the Subcommittee is the final matrix. The Board's interest in examining various parameters used in dose reconstruction will be met, as the cells of the matrix will fill as the cases are randomly sampled in batches.

Dr. Ziemer suggested looking at the Flow Diagram's parameters in detail to clarify any potential issues and illustrated a few ways to randomly sample.

Discussion continued on methods and issues regarding the random sampling process.

Mr. Elliott recommended that **Mr. Todd Braswell** explain the random sample runs he performed. **Dr. Ziemer** called upon Mr. Braswell.

Mr. Braswell addressed the Subcommittee by explaining case selection documents, which were previously submitted to the Subcommittee members via email. The documents include information on two sets of case selections. Each set contained two random samples of

twenty-five cases and one random sample of fifty cases. In the first case selection, the samples were randomly selected out of the total completed cases; in the second case selection, samples were generated based upon selection criterion percentages. **Mr. Braswell** pointed out the frequency distributions for each set and described how he randomly selected cases according to the probability of causation parameters. **Dr. Ziemer** asked if the second case selection set was sorted first and then randomly selected. In response, **Mr. Braswell** clarified by stating that the cases were stratified by probability of causation percentage, then reiterated the steps he took to generate the samples. First, completed cases with final decisions are identified; then, the cases that had the desired probability of causation parameter are selected, according the specific subset percentage. After the Subcommittee had further discussion on the case selection process, **Dr. Ziemer** noted a few observations regarding the distribution of the output and concluded he thought it worked to meet the interests of the Board.

A motion was made, seconded, and passed to select the first 25 cases at random.

Dr. Ziemer instructed Mr. Braswell to select 25 cases at random, not weighted, according to the probability of causation parameters.

Dr. Ziemer recommended a discussion with regard to apportioning the parameter of cancer risk models and called upon **Mr. Griffon**. **Mr. Griffon** commented that doing proportional

sampling on the 32 cancer models might be unfavorable. **Mr. Russ Henshaw** provided a document on the distribution of all cancers for all claims, which led to further discussion on sampling by apportioning cancer risk models. **Dr. Ziemer** stated that determination for the final numbers representing cancer risk models could be reserved for a later time.

Mr. Griffon recommended discussing the parameter of facility. **Dr. Ziemer** noted that facilities could be sampled proportionally according to the claims as based on the previous discussion. **Mr. Griffon** noted that proportionally sampling Department of Energy (DOE) facilities is reasonable; however, Atomic Weapons Establishment (AWE) facilities need to be addressed and wondered if they should be grouped based on available information with assistance from NIOSH. **Dr. Jim Neton** added that many AWEs are primarily uranium operations and represent a distinct category. A basis was established to group together the AWE sites with smaller claims for sampling purposes. **Mr. Griffon** noted that he would update the document on the case review process based on the current numbers. **Dr. Ziemer** ended the discussion by stating that sampling would be proportional to total claims for large DOE and AWE facilities and that smaller sites would need to be grouped together.

Dr. Ziemer asked the Subcommittee if they were ready to settle on an overall recommendation.

A motion was made to adopt the structure as shown in the "Flow Diagram of Case Selection Procedure." The motion was seconded by Dr. Antonio Andrade.

Dr. Henry Anderson recommended a friendly amendment showing 0 to 45 (which by implication is really 44.99); 45 to 49.99; and greater than 50, sample based proportionally on total claims under the facilities category in the "Flow Diagram of Case Selection Procedure."

Dr. Ziemer noted the friendly amendment was a strategy of where to start. **Dr. Anderson** asked if these were their goals.

Dr. Ziemer asked if the Subcommittee agreed with the sample proportions for the duration of employment category, which are 0 to 1 year (15%); 1 to 5 years (25%); 5 to 10 years (25%); 10 to 20 years (25%); and greater than 20 years (10%). **Dr. Ziemer** made a clarification stating, "when we say 1 to 5 it means 1 to 4.9 years." **Mr. Griffon** commented the "0 to 1 years" might be skewed based upon the potential for non-monitoring of radiation exposure. **Dr. Ziemer** replied that they could be adjusted.

The Chair asked if there was agreement to adopt the modifications to the sample proportions for the duration of employment category in the "Flow Diagram of Case Selection Procedure." Without objection, the Subcommittee agreed.

Dr. Ziemer asked if anyone wanted to make a motion to determine how many cases will be examined initially.

A motion was made by Mr. Griffon to start with 25 cases and do a random selection, not a probability of causation-weighted selection. Motion died for lack of a second.

Dr. Ziemer noted that a rationale is needed for random selection to fill the matrix. The Subcommittee continued discussion. **Dr. Ziemer** noted that within SC&A's task, the intent is to review approximately 2.5% of the total number of cases and this is a working value. The 25 would be the starting point and used to learn how well the proposed process works; it is not the full sample because the cases are going to continue to rise.

By unanimous consent, the Subcommittee agreed to start the case selection process with a random sample of 25 cases.

Dr. Ziemer inquired if the "Draft Procedure for Selecting and Tracking Dose Reconstruction Cases" is an explanation of the "Flow Diagram of Case Selection Procedure." **Mr. Griffon** confirmed that it was but it will need to be edited. **Dr. Ziemer** requested that **Mr. Griffon** make the modifications to the 'Draft Procedure for Selecting and Tracking Dose Reconstruction Cases' document before it is presented to the Board and that **Mr. Braswell** randomly select the 25 initial cases for review.

Dr. Ziemer stated the procedure for assigning board members to work with SC&A needs to be established. **Dr. Andrade** added that the procedure would need to be done at the full Board meeting due to conflict of interest considerations. **Dr. Ziemer** agreed.

Mr. Elliott commented that at the working group level in Cincinnati, an agreement was made that NIOSH would produce CDs with the cases for panel members to review containing all Privacy Act information. **Mr. Elliott** stated the board members would be held accountable for protecting the confidential information of cases. **Mr. Elliott** inquired about the make up of the panels with regard to case assignments and conflicts of interest among Board members. **Dr. Anderson** responded that a team would consist of two board members and one contractor. **Dr. Andrade** stated that is just the minimum and they can adjust upward if necessary. **Dr. Anderson** noted the teams should stay together. **Mr. Elliott** commented it might be constraining due to conflict of interest. **Mr. Griffon** added that the review panels should be flexible due to conflict of interest issues.

Dr. Ziemer asked **Dr. John Mauro** how many individuals would be involved in reviewing the 25 cases. **Dr. Mauro** stated he has five case managers, whom are senior health physicists, and a total staff of thirty people. **Dr. Mauro** addressed SC&A's plan for reviewing the cases. SC&A is planning to receive twenty cases every two months over a six-month period. Five case managers, whom are experts in external and internal dosimetry, are designated as case managers for the case reviews. Each of the five case managers will read the initial 20 cases, and then they will meet to allocate four cases to each of the five case

managers. The allocation will be based on the technical background, primarily internal dosimetry. Once the case manager learns the details of the case, he or she will call upon the expertise needed. In each case, the manager will have a schedule and a budget for conducting reviews. Once a comment drafting stage is reached, each case manager will provide comments on a given case at a roundtable discussion. As mentioned in the proposal, SC&A will invite someone from NIOSH and the relevant Board members to sit in on the roundtable discussion. This is similar to what they are doing with the site profiles, and provides an opportunity for fact finding and offering of other perspectives or points of view. **Dr. Mauro** concluded they are open to recommendations on this proposed process.

Dr. Ziemer noted each SC&A team member will have four cases and each case will have two board members. The two board members for each team will need to avoid conflict of interest issues when reviewing cases. **Dr. Ziemer** noted most of the board members are not dosimetry experts and the Board is relying on SC&A for this expertise. **Dr. Ziemer** added that any two board members cannot speak for the Board and noted their role is to bring comments back to the Board regarding each case reviewed in conjunction with their contractor panel member. **Dr. Ziemer** requested a legal point of view in terms of what the board members can do with respect to interacting with the contractor. **Ms. Liz Homoki-Titus** stated they are a working group. **Dr. Ziemer** reiterated that the two board members could not act on behalf of the Board. **Ms. Homoki-Titus** confirmed that and stated they are bringing a work product back to the Board.

Dr. Ziemer asked **Mr. Elliott** and **Dr. Neton** if there is a need for NIOSH to attend the roundtable meetings **Dr. Mauro** described or if they would like to have an early draft of the findings. **Mr. Elliott** responded that an opportunity to provide response for clarity, technical accuracy, and any additional information that might lend itself to the audit would be welcomed. **Mr. Elliott** recommended the opportunity for that input occur before the report is presented in final form. **Dr. Neton** requested to have a factual review prior to the roundtable discussion and before the report is presented in final form, which is similar to the process used for site profile reviews. **Dr. Mauro** indicated he was in favor of sending the preliminary review comments to NIOSH to look over and to have a conference call to validate the understanding of the comments or report. This process would parallel the site profile reviews. **Dr. Mauro** added he is anticipating a two to three day meeting to go over the preliminary review his team will have developed. **Dr. Anderson** added he would like to hear NIOSH's input at that meeting. **Dr. Neton** inquired if the meeting could be done by teleconference and if this would be the process regardless of whether the reviews are basic, advanced, or blind. **Dr. Ziemer** responded that the basic reviews would be done first. While the findings are still being formulated, **Dr. Ziemer** stated the review comments have to be solidified at a closed session at least one day prior to the Board meeting, so a recommendation can be brought to the Board. **Mr. Griffon** requested the board members interact with the case manager prior to the Board meeting via email or telephone in order to give their input. **Dr. Ziemer** confirmed questions could be raised early on in the review process. **Mr. Elliott** addressed the protection of privacy regarding the panel's interaction on

individual cases and indicated a closed session discussion would be well suited to protect the privacy of the individuals.

Dr. Ziemer indicated that if the Board approves the process then the cases could be assigned in open session revealing only the facility represented by a case. This would resolve conflict of interest issues and provide the necessary amount of transparency.

Dr. Ziemer commented it would be good for both the Board and SC&A to see how the site profiles interplay with the cases.

Dr. Andrade inquired how advanced review cases would be selected. The Subcommittee proceeded with discussion on the topic. **Dr. Ziemer** indicated they might want to start an advanced review on a case or two depending on the complexity of the case. **Mr. Griffon** added that having a combination approach where cases could be selected up-front based on certain parameters would present an opportunity to select cases for advanced review. **Dr. Ziemer** noted modifications to the recommendation as having 25 randomly selected cases where assignments will be developed and take the first 20 cases that make sense to review. **Mr. Elliott** requested clarification on whether the first cases would be reviewed as basic or not. **Dr. Ziemer** indicated an option would be given to do one or two advanced reviews depending on the details of case selection and those represented in the first 25 cases. **Dr. Ziemer** summarized that the board members for each team would have an opportunity to

comment early in the review process and be available for SC&A's roundtable discussion. A closed session would be needed the day prior to the next Board meeting. The draft summary report will be established from SC&A's roundtable discussion then sent to NIOSH for input on clarity and accuracy. **Mr. Elliott** confirmed NIOSH would have two opportunities of contact to provide factual accuracy during the review process, once during the roundtable discussion and once after the draft summary report have been developed. **Dr. Ziemer** added a closed session would be needed for review of the final summary report.

Mr. Elliott commented the appearance of the final product needs consideration. **Mr. Elliott** added the Secretary of HHS and Director of NIOSH is looking for recommendations from the Board's review. These recommendations and any summary findings will have to be decided prior to an open Board meeting in a closed session because it will be pre-decisional and deliberative. **Dr. Ziemer** noted that the summary report would be specific in looking for patterns and delineating the summary of findings, which would be addressed at a full Board closed session. **Mr. Elliott** reiterated a closed session is needed due to the implications of discussing individual cases particularly in the development of summary findings.

Dr. Anderson repeated the process of the case reviews. Once the Board members approve the final draft, the Board would take the comments from the 20 cases reviewed and compile them into a single report, which then could become a report of the Subcommittee. **Dr. Ziemer** remarked it could identify issues or concerns without relating them to a specific case,

which could be generated in advance and taken to an open session. **Dr. Ziemer** added there is going to be a roll up of the findings at the end, envisioning that this would to be done as a group. **Mr. Griffon** commented that having a closed session would allow SC&A to present the individual case reports to each set of panel members and to draft a roll up summary report to present to the Board. The Board can review, vote, and then present that report to the public. **Ms. Homoki-Titus** noted if there is conflict of interest during the discussion of the individual case reviews, that person must step away from the table and cannot vote on that particular issue.

With no further business to come before the Subcommittee, the meeting was adjourned.

End of Summary Minutes

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NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

I hereby confirm these Summary Minutes are

accurate, to the best of my knowledge.

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Paul L. Ziemer, Ph.D., Chair

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Date

SUBCOMMITTEE FOR DOSE RECONSTRUCTION AND SITE PROFILE REVIEWS FIRST MEETING: ACTION ITEMS

IDAHO FALLS, IDAHO
August 23, 2004

NIOSH/CDC Advisory Board on Radiation and Worker Health's
Subcommittee for Dose Reconstruction and Site Profile Reviews
August 23, 2004

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The following documents, developed by a working group, were presented, discussed, revised, and voted on during the First Subcommittee Meeting. A final version of the documents was recommended to the Board on Wednesday, August 26.

Procedure for Selecting and Tracking Dose Reconstruction Cases
Procedure Number: ABRWH-CaseSelection-001
Effective Date: 8/24/04

1. The Board will establish a Case Selection Matrix based on parameters outlined in Attachment 1 with approximate weights (number of cases) for each parameter of interest. The number of cases to be selected which meet each criterion will be considered as guidelines for the case selection. Actual numbers of cases reviewed for each field may vary. For example, the Boards initial matrix may suggest 30 cases be reviewed for the Hanford site however, the Board may decide to either review fewer Hanford cases or more cases depending on the nature of the case load.

2. NIOSH will provide the Board, or the Dose Reconstruction Sub-Committee with updates on finalized cases available for review. This data will include the following information: case number (or de-identified number linked to case number), facility, cancer type, risk model, decade first employed, number of years employed, and final calculated POC (99^{th} percentile POC value).

3. The Board or Dose Reconstruction Sub-Committee will request NIOSH to make a random selection of cases (Board will determine the number of cases for each batch of cases to be reviewed; Board will determine whether all cases will be re-sampled each time a batch of cases is selected) meeting the POC criteria (see attachment).

4. The Board or Dose Reconstruction Sub-Committee will review each batch of cases to determine appropriateness of the batch based in part on the criteria identified within the flow diagram (see attachment). This procedure is intended to give the Board or Sub-Committee flexibility in selection since all cases projected to be available will not be available at the time of the initial sampling. This flexibility is also necessary since certain criteria (job type, radiation type, etc. – see note on flow diagram) can only be determined by looking at the

hard copy records within the case (the parameters are not searchable fields within the NIOSH database).

5. A tracking matrix will be developed and maintained by the Boards subcontractor. The batch sampling discussed above will be used to fill in the cells within the matrix. For example, if it is determined that overall the Board wishes to review 30 cases from Hanford this parameter will be tracked until that number is completed. This data will be tracked for the Board, or designated Sub-Committee by the Boards subcontractor

6. The Board will provide written updates on cases reviewed at each meeting and NIOSH will make this data available to the public. This information will only include the statistics of the cases reviewed. Review reports are discussed in the Procedure for Case processing. .

NIOSH/CDC Advisory Board on Radiation and Worker Health's
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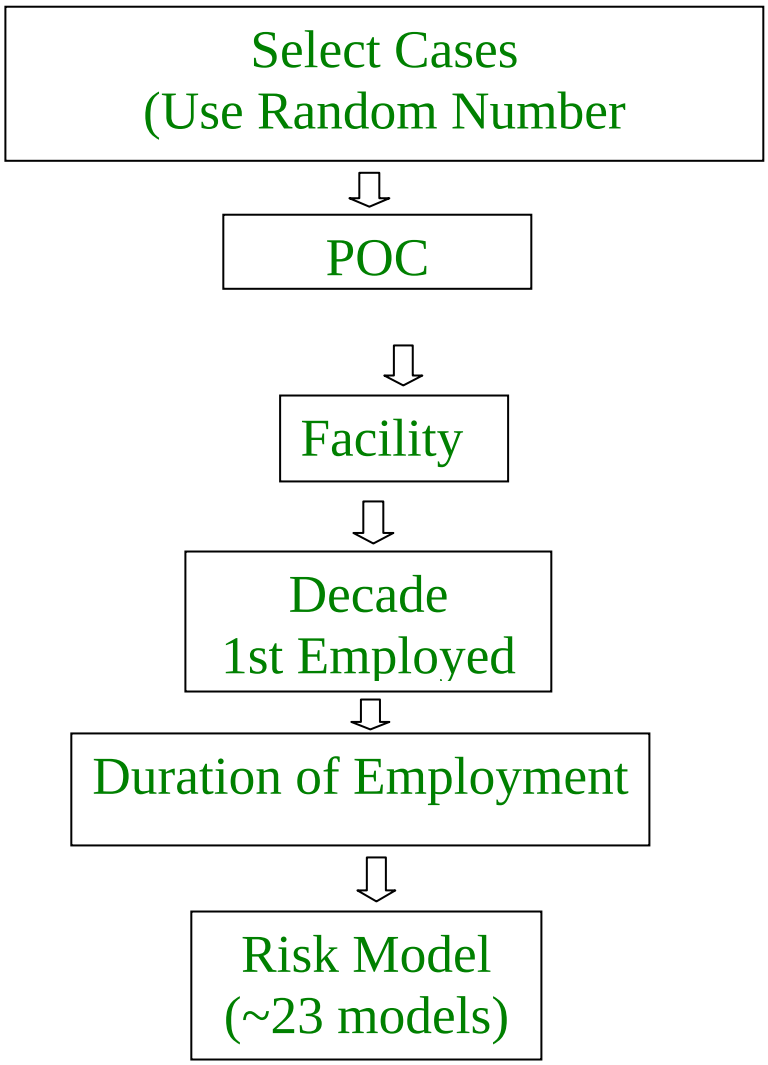
Flow Diagram of Case Selection Procedures



0-40% (sample 40% of cases), 40-49.9% (sample 40%), >50% (sample 20%)

Sample based on total claims from all DOE facilities, Large AWE facilities, and groupings of smaller AWEs

Fill Cells as follows: 40s(10%), 50s(25%), 60s(25%), 70s (25%), 80s (10%), 90s (5%)

Fill cells as follows: 0-1 year (25%),. 1-5 years (25%), 5-10 years (25%), >10 years (25%)

Apportion by complexity or metabolic factors

NOTE: We will also track other parameters associated with the cases but not in the database. These parameters include: Cases using co-worker data, Monitored vs. Un-monitored, job category, work area or building, and primarily internal dose or external dose.

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