COWORKER DOSE MODELING

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I. BACKGROUND

- ORAUT-RPRT-0053 discusses methods for developing coworker models. Statistical tests are recommended to decide if a single coworker model is appropriate for all workers at a site, or if separate coworker models are necessary for different sub-groups of workers (strata).
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- Several ORAUT documents are based on the analytical methods proposed in RPRT-0053. These documents compare coworker models for construction trades workers (CTWs) and non-construction trades workers (NCWs) at the Savannah River Site (SRS).
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  - ORAUT-RPRT-0055, *A Comparison of Exotic Trivalent Radionuclide Coworker Models at the Savannah River Site*, July 2012
  - ORAUT-RPRT-0056, *A Comparison of Neptunium Coworker Models at the Savannah River Site*, August 2012
  - ORAUT-RPRT-0058, *A Comparison of Mixed Fission and Activation Product Coworker Models at the Savannah River Site*, September 2012.
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- This presentation includes examples drawn from our review of these documents.
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II. DATA ISSUES

A. SAMPLING PROTOCOL ISSUE (Finding 4)

- Strata comparisons are valid only when the sampling protocols were the same.
- Issue applies to datasets reduced using the One Person-One Sample (OPOS) procedure and to raw datasets of samples.
- If sampling protocols differ, valid statistical comparisons cannot be made.
- *Example:* If monitoring is incident-driven for one group of workers and not for the other, the hypothesis tests do not provide a valid comparison.
- NIOSH states in RPRT-0056 and RPRT-0058:

  CTWs are potentially subject to different bioassay practices than other workers. CTWs, many of whom are contractors, commonly submit bioassay samples after suspected uptakes and at the completion of jobs.

  This is in contrast to other workers, especially those employed directly by the prime contractor, who are more likely to be on a routine bioassay program in addition to submitting bioassay samples after suspected uptakes.

B. REPRESENTATIVENESS AND COMPLETENESS (Finding 2)

- The completeness and representativeness of the data available for coworker model is not addressed in ORAUT-RPRT-0053. If the unmonitored workers are from a different population, the applicability of a coworker model derived from monitored coworkers would be in question.
- Characteristics of monitored and unmonitored populations should be the same. **The relative exposure potential of the monitored versus unmonitored workers needs to be demonstrated rather than assumed.**
- The methods proposed in ORAUT-RPRT-0053 for analyzing the coworker datasets require verification that:
  - The available coworker data are representative of all groups of workers
  - The manner of use of the data is claimant favorable for the specific datasets to which the method is applied

  A sound statistical methodology is subject to these two important caveats.
- **To this end, it is necessary to examine subgroups of CTWs. Data for the coworker model must be representative of these groups, and there must be sufficient data for pairwise comparisons with other monitored workers.**

C. NUMBER OF STRATA (Recommendation 3)

- **NIOSH has not made comparisons of CTW subgroups.**

- Analysis of SRS CTWs by job type and by area of work (SC&A 2010a, 2010b) indicates that subgroups of CTWs have unique distributions of exposure and are not from the same distribution as NCWs or other CTW subgroups.

- Multiple pairwise comparisons would be required for the CTW analysis. Sufficient data (**at least 30 samples for each category**) would be required in each job/area category for which a coworker model is to be constructed. **The hurdle is sufficient data for such comparisons.**

D. WORKERS CHANGING JOBS (Finding 7)

- The statistical tests for comparing two strata require that the samples in each group be independent.

- If a worker in one group is exposed to radionuclides with long retention in the body and then changes jobs and becomes part of the other group in the same period, the OPOS values are correlated for this worker. (Note that OPOS aggregation periods can be as long as 3 years.)

- This correlation not only violates the assumptions of the tests, but also creates a bias toward a decision of "No Difference" between the two groups. If CTW and NCW are being compared, it is essential that the job designation has not changed during the period of OPOS aggregation.

- NIOSH has not investigated whether changes of workers from one stratum to another occurred during the period of OPOS aggregation and, if so, how such data are to be handled.

III. METHODOLOGICAL ISSUES

A. POWER CONCERNS (Finding 8)

- NIOSH has not provided any measure of the power of the hypothesis test procedures to detect differences within the worker population. This deficiency should be corrected before the tests are adopted as an appropriate procedure for coworker models.
- Accepting the null hypothesis could often be very claimant unfavorable if the available data do not provide adequate power for the test.
- NIOSH has stated that 30 samples in each strata is sufficient for a valid comparison. We investigated this issue further during our review of the SRS application documents noted above. The following very general results are reported in our review of the neptunium coworker model.
- Table 1 and Figure 1 show results of simulations performed to show the power of the WRS test when using 30 samples to compare lognormal distributions which differ by a factor of 2.73. The samples include 24% nondetects. The GSDs are assumed the same for the two distributions. Simulation was conducted using Crystal Ball.

A. POWER CONCERNS (Finding 8 - continued)

- Results: **Type 2 error rates can be very high (15–35%) when using the 95% confidence level (α=0.05) if the GSDs exceed 4.** If the confidence level is reduced to 90% (α=0.10), the Type 2 error rate is maintained below 20% up to a GSD of 6. If the confidence level is 80% (α=0.20), the Type 2 error rate maintained is below 10%.
- **Overall, SC&A concludes that the NIOSH method of determining that there are no significant differences based on the available data would often lead to very claimant-unfavorable results**.

SIMULATION RESULTS

Table 1. Type 2 Error Rate of WRS Test using 30 Samples from Two Lognormal Distributions: LN(0,1) and LN(1,1)

		GSD			
α	6	5	4	3	2
0.05	0.35	0.27	0.16	0.04	<0.001
0.10	0.22	0.16	0.09	0.02	<0.001
0.20	0.11	0.07	0.04	0.006	<0.001
0.25	0.09	0.05	0.02	0.003	<0.001

n1=n2=30, 24% nondetects, and GM2/GM1 = 2.73
Shaded region of table has Type 2 Error rate ≤10%

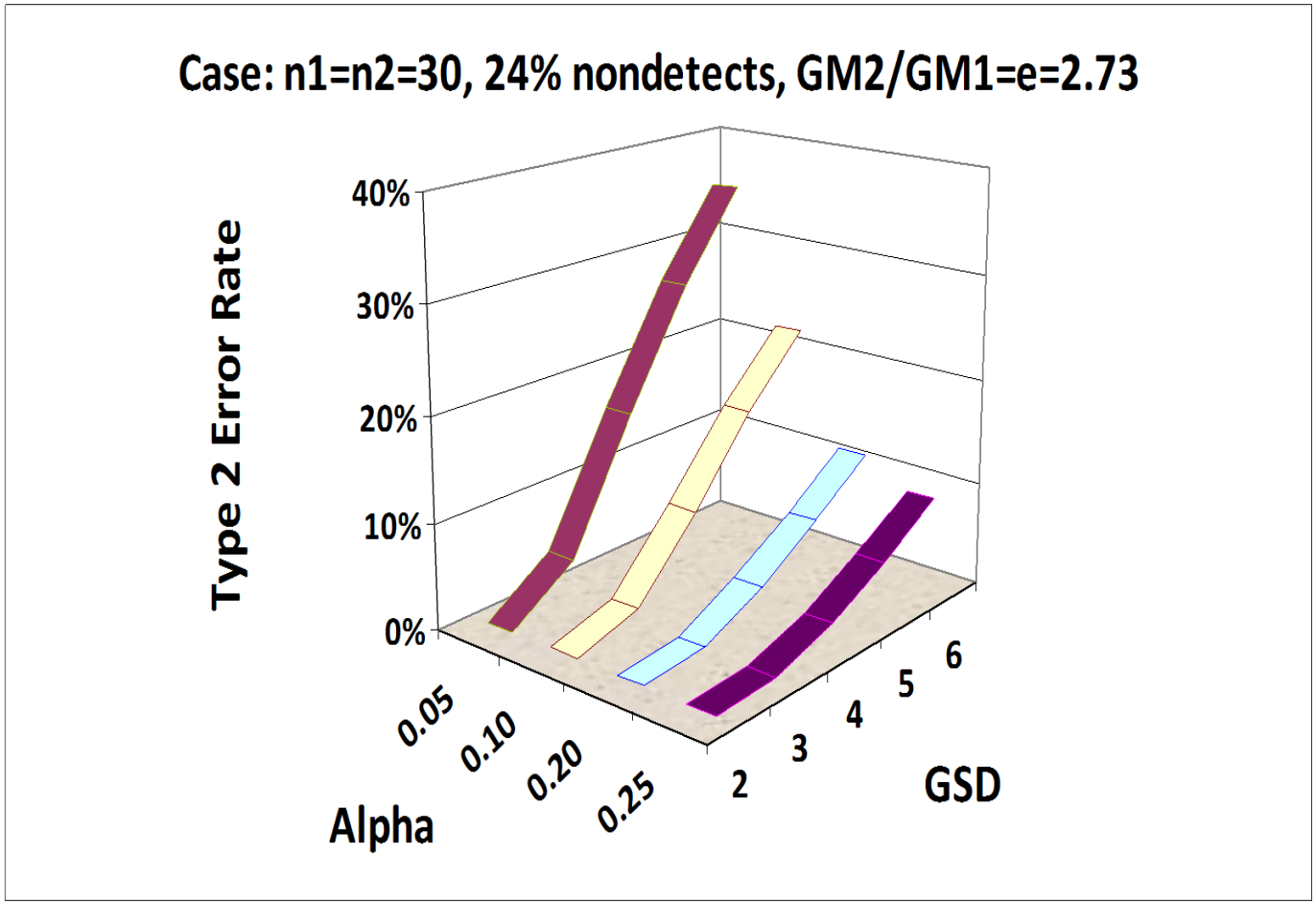

Figure 1. Type 2 Error Rate of WRS Test using 30 Samples from Two Lognormal Distributions: LN(0,1) and LN(1,1)

B. SMALL SAMPLE SIZES (Finding 6)

- **Power of the statistical tests to detect differences given the limited quantity of data with high proportion of nondetects has not been established.** The size of difference that can be detected reliably by the statistical tests was not examined. This deficiency should be corrected before RPRT-0053 is adopted as an appropriate procedure for evaluating coworker models.
- If the quantity of data is insufficient to provide adequate power of resolution for the test, differences may go undetected. Accepting the null hypothesis in this case could often be very claimant unfavorable.
- The Data Quality Objectives (DQO) process should be used to define the Gray Region for the test, and to balance Type 1 and Type 2 decision errors. The MARSSIM procedure for conducting hypothesis tests is depicted in Figure 2.
- In our review, we examined SRS Logbook Np OPOS data for 1961–1989 (Table 2). The WRS test shows slightly less power than the t-test for these datasets. We found there are sufficient data in 1961–1963 to detect differences as small as a factor of 2. The year 1985 produced anomalous results in this analysis. **In many years, the WRS test cannot reliably detect differences smaller than a factor of 4 to 10 in the CTW/NCW ratio of GMs.**
- Larger differences have a 95% or better chance of detection. Smaller differences cannot be detected reliably with the available data.

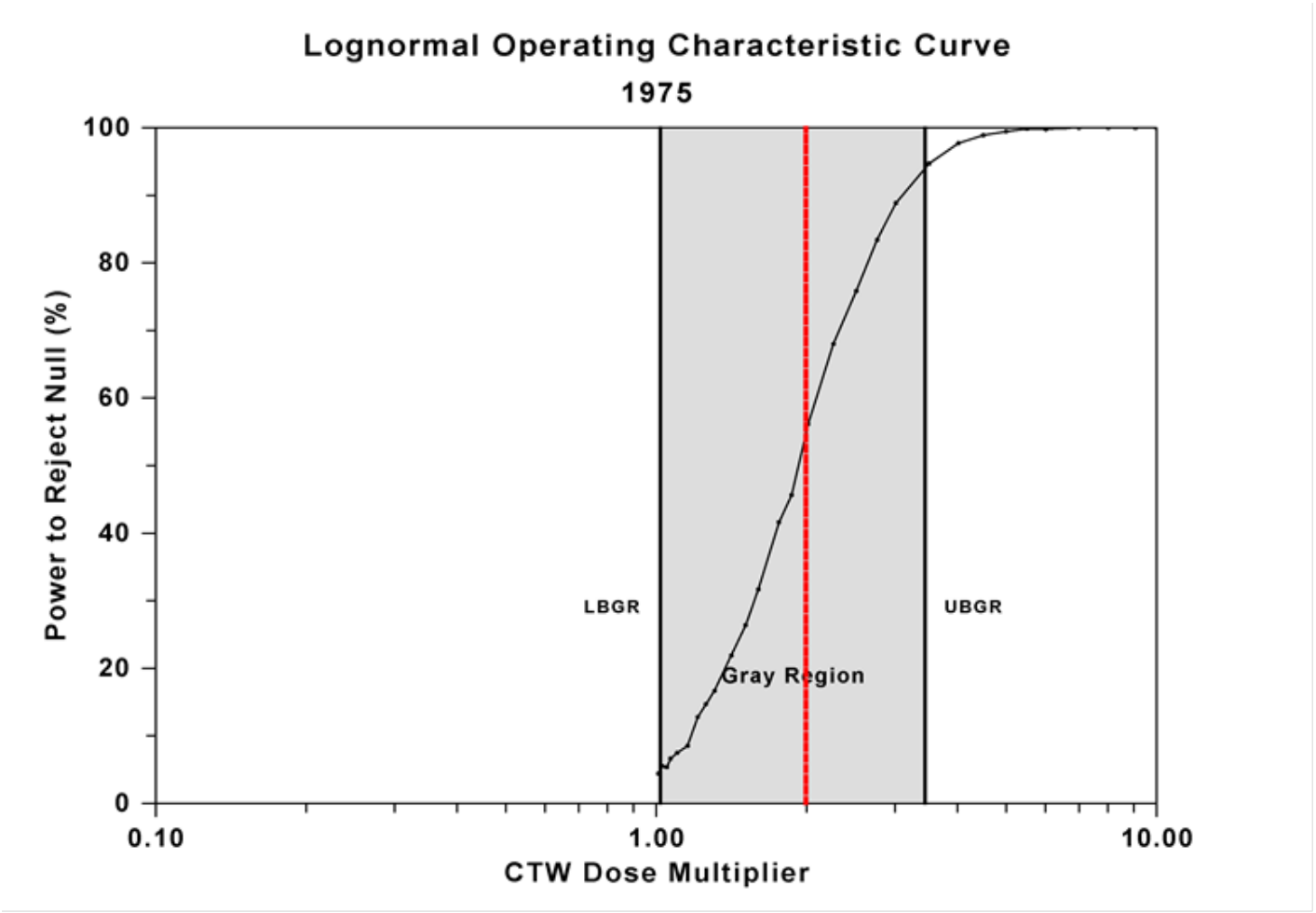

Figure 2. The DQO Process is Used to Define the Gray Region for the Test. Power is Low and Type 2 Error Rates are High Below the Upper Bound of the Gray Region (UBGR)

Table 2. Sample Sizes and Upper Bound of the Gray Region (UBGR) for Test of "No Difference" Hypothesis with SRS Logbook Np OPOS Data 1961–1989

	Number of Samples		Upper Bound of Gray Region (UBGR)	
Year	NCW	CTW	t-Test	WRS Test
1961	252	57	1.5	1.5
1962	734	175	1.5	1.5
1963	362	82	2.0	2.1
1974	58	10	3.5	3.8
1975	64	21	3.4	3.8
1977	43	11	8.4	10.2
1978	73	19	3.9	4.6
1979	55	12	4.9	4.6
1980	87	19	3.8	4.3
1981	99	23	4.4	4.5
1983	82	24	3.2	3.4
1984	92	25	3.8	4.1
1985	62	13	29.0	57.4
1986	65	13	5.5	5.6
1987	81	15	6.4	8.6
1988	77	13	5.0	5.0
1989	69	17	7.9	11.0

C. LEVEL OF CONFIDENCE (Finding 5)

- The test procedures recommended in RPRT-0053 require a high level of confidence before deciding that two worker groups are significantly different.

- This is not claimant favorable, since there is a trade-off between high confidence and power to detect differences given a fixed sample size. A high level of confidence reduces the power of the test to detect differences.

- Conducting the 2-sided test of the “No Difference” hypothesis at a 90% level of confidence would result in lower Type 2 error rates and be more claimant favorable.

D. 1-SIDED VERSUS 2-SIDED TESTS (Recommendation 1)

- RPRT-0053 recommends using 2-sided tests to determine if there is a significant difference between groups of workers. The null hypothesis for these tests states there is "No Difference" between the two groups. **This form of test is not claimant favorable at SRS, as it places the burden of proof on the CTW claimants to prove that a significant difference exists.**

- In the specific case of the SRS SEC for CTWs, a 1-sided test is more appropriate, as it addresses directly the question at hand: **Are the CTW samples higher than the NCWs, or not?** There are two possible forms of null hypothesis for a 1-sided test:

$$(1) \qquad H_0: F_{NCW} > F_{CTW}$$

or

$$(2) \qquad H_0: F_{NCW} < F_{CTW}$$

D. 1-SIDED VS. 2-SIDED TESTS (Recommendation 1 - continued)

- **With either selection, the null hypothesis may not be rejected simply because there are insufficient data.** In English, the two options are as follows.

  (1) *Assume that NCW exceed CTW, and look for evidence in the data that this assumption is false* (i.e., **CTW are lower, until proven higher**)

  This option is not claimant favorable in the SRS applications, as it places the burden of proof on the CTW claimants to provide sufficient data to prove their exposures were higher.

  (2) *Assume that CTW exceed NCW, and look for evidence in the data that this assumption is false* (**CTW are higher, until proven lower**)

  It is more claimant favorable to choose the second form of null hypothesis for a 1-sided test, as it places the burden of proof on NIOSH to provide evidence that the NCW distribution bounds the CTW distribution. **Groups of workers with suspected high exposures should be considered different in the absence of strong evidence that they are not.**

- NIOSH might consider using the second form of the 1-sided hypothesis test instead of the 2-sided test now used. The non-parametric Peto-Prentice test is more generally applicable than the parametric MCPT, and may be applied using the more claimant-favorable 1-sided null hypothesis number (2) above. This is more likely to result in a claimant-favorable coworker model.

REFERENCES

ORAUT-RPRT-0055: *A Comparison of Exotic Trivalent Radionuclide Coworker Models at the Savannah River Site*, July 2012

ORAUT-RPRT-0056: *A Comparison of Neptunium Coworker Models at the Savannah River Site*, August 2012.

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