Office of Compensation Analysis and Support Program Evaluation Report	Document Number: OCAS-PER-008 Effective Date: 04/12/07
Modification of NIOSH-IREP lung cancer risk model: effect of	Revision No. 0 Page 1 of 4
"combined" lung model on non-compensable lung cancer claims	
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ISSUE AUTHORIZATION DATE	EFFECTIVE DATE	REV. NO.	DESCRIPTION
04/12/07	04/12/07	0	New document to report the impact of the NIOSH-IREP lung cancer model on non- compensable cases completed before 2/28/06

1.0 <u>Description</u>

The "combined" lung cancer risk model was introduced on 02/28/06 via the release of NIOSH-IREP Version 5.5, followed by v5.5.1 on 05/16/06. The combined lung model is programmed with two different lung cancer risk models: the NIOSH-IREP model, plus an alternative risk model created by the National Cancer Institute for use in NIH-IREP, another version of IREP (referred to hereafter as the "NIH" model). For each cancer of the lung, trachea, or bronchus, NIOSH-IREP now calculates separately the probability of causation (PC) produced by each of the two risk models and reports the higher PC at the upper 99th percentile credibility limit as the PC value of record for the claim. NIOSH-IREP v5.5 and v5.5.1 also incorporate a bias correction factor for random errors in dosimetry for "never smokers" exposed to radon. Due to a programming oversight, this correction had been omitted for "never smokers" and was applied only to smokers in earlier versions of NIOSH-IREP. NIOSH-IREP v5.5 corrected this error.

This "combined" lung cancer risk model was endorsed by the Advisory Board on Radiation and Worker Health, and can result in no lower PC value for the same set of claim inputs than had been calculated under previous versions of NIOSH-IREP (versions 5.4 and earlier).

For a more detailed description of the new combined model, including the background of and rationale for the modification, please refer to OCAS-PEP-008, dated 12/07/06.

Effective Date: 04/12/07	Revision No. 0	Document No. OCAS-PER-008	Page 2 of 4
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2.0 <u>Evaluation</u>

A database search identified 920 non-compensable (PC<50% at the upper 99th percentile credibility limit) lung cancer claims that had been processed prior to the adoption of the combined lung model. A preliminary evaluation was conducted and the results were reported in OCAS-PEP-008. The preliminary evaluation consisted of running each of the 920 claims (729 [79%] single cancer claims, 191 [21%] multiple cancer claims) in NIOSH-IREP v5.5.1 (single IREP run at 2000 iterations) to determine the initial effect of the "combined lung model" on PC.

The preliminary results reported in the program evaluation plan (OCAS-PEP-008) indicated that the PC increased in 73 of the 729 single cancer claims (95 total claims with an increased PC, including 22 increases in the multiple cancer claims), and that 11 of the 95 claims had a new PC value of 45% or higher and would require further evaluation. However, a subsequent review conducted for this PER revealed that a mistake had been made in the PEP. Actually, the PC increased in 77 of the single cancer claims (99 increases in total, including the multiple cancer claims). However, the PC remained below 45% in all 4 of the additional claims, so no further evaluation of those claims was required. The 4 increases were all due to the NIH lung model rather than to the radon bias correction factor.

As expected, the alternative NIH lung cancer risk model produced the higher PC value for the vast majority (95, or 96%) of the 99 affected claims. Of these 95 claims, 74 (78%) were single cancer claims and 21 (22%) were multiple cancer claims. However, the 21 multiple cancer claims included 28 separate lung cancers. Thus, the total number of lung cancers among all claims for which the NIH lung model produced a higher PC (versus the NIOSH lung model) was 102. The mean and median increase in PC produced by the NIH lung model versus the NIOSH model for the 102 lung cancers was 1.90 and 1.30 percentage points, respectively (range = 0.01 to 12.58 percentage points). The NIH lung model produced a *lower* PC value at the upper 99th percentile credibility limit than the NIOSH lung model for 825 (90%) of the 920 previously non-compensable claims. Corrected results of the preliminary evaluation are displayed in Table 1.

Of the 99 claims with increased PC values, there were only 4 claims in which the NIOSH v5.5.1 lung model produced a higher PC than the NIOSH lung model used in earlier versions of NIOSH-IREP (v5.4 and earlier). The PC increases for these 4 claims were due to the radon bias correction factor (see OCAS-PEP-008, Section 1.0). The PC increases due to the bias correction factor were 1.01, 5.23, 5.29, and 6.47 percentage points, respectively (mean increase = 4.50; median = 5.26).

Effective Date: 04/12/07	Revision No. 0	Document No. OCAS-PER-008	Page 3 of 4
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Table 1: Preliminary evaluation of non-compensable lung cancer claims processed before 2/28/06: initial effect of NIOSH-IREP "combined" lung cancer risk model on probability of causation (PC) based on single IREP run at 2000 iterations

Type of Claim	Number of Claims	<u>No</u> PC Increase	PC Increase	Increase Due to NIH Model	Increase Due to Bias Correction Factor	New PC <45%	New PC = 45 - 49.99%	New PC ≥ 50%
1 cancer	729	652	77	74	3	70	3	4
>1 cancer	191	169	22	21	1	18	4	0
Totals	920	821	99	95	4	88	7	4

As described above, the PC increased initially (single IREP run at 2000 iterations) in 99 of the 920 lung claims. The new PC values for 88 (89%) of the 99 claims remained below 45% and required no further review. However, 11 (11%) of the 99 claims had a new PC value of 45% or higher and merited further evaluation. Each of the 11 claims with a new PC \geq 45% required 30 IREP runs at 10,000 iterations to establish the average (arithmetic mean) PC value and/or a rework of the dose reconstruction, depending in part upon the original dose reconstruction approach used for the claim. Since 4 of these 11 claims had more than one cancer, 30 IREP runs were required for each cancer (i.e., including cancers other than lung) for each of the 4 claims. The final outcome for each of the 11 claims is reported in Table 2.

Table 2: Final evaluation of 11 claims in which the PC value had increased to ≥45% after
single IREP run at 2000 iterations using NIOSH-IREP v5.5.1 "combined" lung model

	Original	Original	Interim	Interim	
Claim	DR	Claim PC	Claim PC	Claim PC	Final Claim Outcome
No.	Approach	(1 IREP	(1 IREP	(30 IREP	
		Run)	Run)	Runs)	
1	Overestimate	45.91%	46.05%	45.26%	PC remained below 50%
2	Overestimate	45.50%	45.79%	44.94%	PC remained below 50%
3	Best Estimate	46.14%	50.94%	50.05%	PC exceeded 50%
4	Overestimate	38.28%	48.08%	43.33%	PC remained below 50%
5	Overestimate	46.56%	53.03%	49.15%	PC fell below 50% after rework
6	Overestimate	43.81%	49.04%	48.93%	PC remained below 50%
7	Overestimate	44.38%	56.15%	N/A	Reworked for reasons unrelated to
					lung model; PC decreased to 23.29%
8	Overestimate	34.35%	46.93%	47.44%	PC remained below 50%
9	Overestimate	44.60%	47.56%	52.17%	After "best estimate" rework,
					PC=52.08% (single IREP run)
10	Overestimate	41.16%	45.08%	45.87%	PC remained below 50%
11	Overestimate	42.72%	53.22%	N/A	PC decreased to 42.82% after rework

Effective Date: 04/12/07	Revision No. 0	Document No. OCAS-PER-008	Page 4 of 4
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3.0 <u>Resolution/Corrective Action</u>

Of the 920 evaluated lung cancer claims, the "combined" lung cancer risk model produced <u>no</u> PC increase in 821 claims. Of the 99 claims with an increased PC value at the upper 99th percentile credibility limit, the new PC for 88 of the 99 claims remained below 45% and required no further evaluation. Of the 11 claims that merited further evaluation (i.e., PC≥45% after a single IREP run at 2000 iterations), the final PC value for 9 of the claims remained below 50% (Table 2) after being reworked and/or subjected to 30 IREP runs.

The final PC increased to \geq 50% for only 2 of the claims (Claim #3 and Claim #9, Table 2). Since the dose reconstruction for Claim #3 was originally performed as a "best estimate," no further review was necessary and the new PC of 50.05% (average value of 30 IREP runs) was considered the final PC result. Claim #9, originally an "overestimate" dose reconstruction, was reworked as a "best estimate." After the rework, a new PC of 52.08% was calculated using the default simulation sample size of 2000 and a single IREP run. Since this new PC value exceeded 52% and was based on a best estimate dose reconstruction, the claim no longer met the criteria for conducting 30 IREP runs and the PC value of 52.08% was considered the final PC result.

Thus, of the 920 non-compensable lung cancer claims completed prior to the 2/28/06 implementation of the "combined" lung cancer risk model, the final PC after reevaluation crossed the 50% compensation threshold in only 2 (0.2%) of the 920 claims. An itemized list has been provided to DOL containing the final evaluation result for each of the 920 claims.

4.0 <u>Reference</u>

1) National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support: OCAS-PEP-008 (Program Evaluation Plan: Modification of NIOSH-IREP lung cancer risk model: impact of "combined" lung model on non-compensable lung cancer claims). December 7, 2006.