Division of Compensation Analysis and Support Program Evaluation Report	Document Number: DCAS-PER-074 Effective Date: 8/5/2016 Revision No. 0
NIOSH-IREP 5.8 UPGRADE	Page 1 of 15

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RECORD OF ISSUE/REVISIONS			
ISSUE AUTHORIZATION DATE	**EFFECTIVE DATE**	**REV. NO.**	**DESCRIPTION**
8/5/2016	8/5/2016	0	New document to determine the effect of the modifying of NIOSH-IREP on previously completed claims.

1.0 Description

The Probability of Causation (POC) analysis for the EEOICPA program is performed using a computer software application known as the NIOSH Interactive RadioEpidemiological Program (NIOSH-IREP). The underlying computational platform of NIOSH-IREP relies on the Analytica Decision Engine (ADE). Because of technical limitations and continuing support issues, it became necessary to upgrade from ADE version 3.0, which has been in use since NIOSH-IREP was originally developed, to ADE version 4.6.1. The new version of ADE uses a different random number generator which results in slightly different POC results from the earlier version. The revised NIOSH-IREP program that incorporates the updated ADE is identified as version 5.8. This PER (DCAS-PER-074) evaluates the effect of applying this version of NIOSH-IREP on previously completed claims. A more detailed discussion of the statistical analyses that were conducted to evaluate the magnitude of this effect is provided in Attachment A of this PER.

2.0 Issue Evaluation

An analysis of the effect of using ADE version 4.6.1 on the POC calculation was performed by the Oak Ridge Center for Risk Analysis (ORCRA), the original developers of the NIOSH-IREP software. An independent analysis was conducted by DCAS with similar results. This preliminary analysis indicated changes in the calculated POC would be small with the maximum difference being less than one percentage point. More details of this analysis are provided in Attachment A.

3.0 Plan for Resolution or Corrective Action

With the projected difference of less than one percentage point, it was decided that rerunning all claims with an original POC between 48% and 50% would encompass all cases that could possibly change to a value greater than 50%. The number of cases meeting this criterion was 117. The minimum and maximum difference in the POC calculated with version 5.8 versus a previous version was -0.77% and 0.56%, with a mean difference was 0.00%. Since all these cases had POCs between 45% and 50%, NIOSH-IREP 5.8 was run 30 times at 10,000 iterations per NIOSH procedures. Of the 117 cases that were rerun, none would now result in a POC greater than or equal to 50%. More detail of the analysis is provided in Attachment A.

NIOSH will provide the Department of Labor with the list of all claims evaluated under this PER. Since none would now result in a POC greater than 50%, NOSH will not request the return of any of the claims.

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Introduction

The previous configurations of the NIOSH-IREP software versions (v.5.7.1 and lower) were using an outdated version of the Analytica Decision Engine (ADE), more specifically ADE 3.0, a version that had been in use since 2002 when the NIOSH-IREP software was originally developed. The ADE 3.0 version of Analytica was not supported any more by the developing company, Lumina Decision Systems, and this issue created some technical difficulties when support was needed for certain features incorporated in the NIOSH-IREP software. In addition to this, when claims with more than 600 rows of exposures were run on the NIOSH-IREP software, most of the time the NIOSH-IREP software was not able to compute a Probability of Causation (PC) value, due to time and memory limitations.

The solution to fix these issues was to upgrade the software used to run NIOSH-IREP by using the latest version of ADE 4.6.1, which can also be run under a 64-bit environment. The upgraded version, denoted as NIOSH-IREP v.5.8, allows for the use of up to 128 GB per calculation, meaning that NIOSH-IREP v.5.8 is now able to handle any claim up to a maximum 1,000 rows of exposure information. In addition to being able to handle claims with large input requirements, the NIOSH-IREP v.5.8 software, which is also hosted on a new 64-bit server, offers speed increases which result in claims being calculated up to five times faster than the claims being run on the previous NIOSH-IREP v.5.7.1 software.

The effect of the software upgrade

One of the main differences between the two Analytica engines (ADE 3.0 and ADE 4.6.1) is in the way the random numbers are generated in the two versions. The algorithm for the random number generator in ADE 4.6.1 is much more efficient that the one used in ADE 3.0, and it also corrects a very small bias that was present in the previous versions.

Here is a description from Lumina regarding the revised sampling procedure:

"A small undesirable bias was discovered in the random shuffling algorithm used in Latin Hypercube sampling (present early versions through Analytica 4.2). The bias introduces a small skew in computed results. The bias is extremely small at large sample size, but can become significant at sample sizes under 10. Analytica 4.3 (and newer versions) eliminates this bias, thus increasing the fidelity of Latin-Hypercube simulations. However, a side-effect of this is that you will find that the random samples generated by distribution functions are shuffled differently than they were in Analytica 4.2, so the precise numbers in your Sample view will be different."

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As a result of this, there are some small differences in the results from the Monte Carlo simulations obtained using the ADE 4.6.1 versus the ADE 3.0 engines. Since the ADE 4.6.1 is using a slightly different number generator than the one used in ADE 3.0, this is causing a small variation in the PC values obtained using the NIOSH-IREP v.5.8 software, versus the PC values obtained using the NIOSH-IREP v.5.7.1 software or any other previous versions of NIOSH-IREP software. While obtaining slightly different PC values is not an issue, NIOSH wanted to evaluate if the compensability for certain claims might be affected as a result of implementing the NIOSH-IREP v.5.8 version.

Preliminary analyses on the effect of changes in PC values

Oak Ridge Center for Risk Analysis (ORCRA)**,** the company that developed and maintains the NIOSH-IREP software under a contract with NIOSH, was tasked with an initial evaluation of the effects on PC values, based on using various exposure scenarios for the different radiation types and cancer models available in NIOSH-IREP, so that NIOSH we will have a better understanding of the magnitude of the expected changes in the PC values. ORCRA selected 62 different tests scenarios, most of them including only one dose scenarios, in order to look at the PC differences obtained from using the two Analytica engines in the NIOSH-IREP software. Several variables were tested, including: genders, cancer types, radiation types, exposure rates, organ dose distribution types, ages at time of exposure, ages at diagnosis, ethnicity (for skin cancers), smoking histories (for lung cancers), radon exposures (for lung cancers), and user-defined uncertainty distribution (random seeds used in the Monte-Carlo simulations). The results obtained by ORCRA showed that the differences in the Avg. PC values between NIOSH-IREP v.5.8 and NIOSH-IREP v.5.7.1, range from -0.18 to 0.29, with a mean value of 0.07, and a median value of 0.08, for these mostly one-dose scenarios.

NIOSH also performed an initial evaluation in order to see how the PC values vary when already completed claims were run on the NIOSH-IREP v.5.8 versus the NIOSH-IREP v.5.7.1. For this purpose, NIOSH randomly selected single cancers claims from the NOCTS database, most of them with the 99th percentile PC values between 45.00% and 49.99%. The claims selected included all the 33 IREP cancer models currently available in NIOSH-IREP software, with a total of 75 single cancer claims being chosen for this evaluation. None of the non-compensable claims previously completed on NIOSH-IREP v.5.7.1 become compensable as a result of running it on the NIOSH-IREP v.5.8. The differences in the Avg. PC values between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, for all the 75 cases, ranged from -0.64 to 0.67, with a mean value of -0.01, a median of -0.02, and a standard deviation of 0.19.

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Both preliminary studies were conducted using the NIOSH-IREP Enterprise Edition versions, with both ADE 4.6.1 and ADE 3.0 engines; in the NIOSH-IREP Enterprise Edition versions, an Avg. PC value from 30 runs using 10,000 iterations is computed for each case.

Table 1 shows the summary statistics for the two preliminary analyses.

Table 1: Summary statistics for the differences in Avg. PC values between IREP v.5.8 and IREP v.5.7.1

Preliminary evaluations	N	Min	Median	Mean	Max
ORCRA evaluation (various exposure scenarios, mostly one dose exposures)	62	-0.18	0.08	0.07	0.29
NIOSH evaluation (NOCTS single cancer claims, mostly with PC values between 45.00% and 49.99%)	75	-0.64	-0.02	-0.01	0.67

Final analysis on the effect of changes in PC values

The NIOSH-IREP software was upgraded from version v.5.7.1 to version v.5.8 on December 16, 2015. Starting on 12/06/2015, all the new claims were run on the NIOSH-IREP software v.5.8, in order to determine the PC values associated with each claim.

For the non-compensable claims already completed on the NIOSH-IREP software v.5.7.1 or one of the earlier versions, there is a very small chance that if those claims were to be run again on the NIOSH-IREP software v.5.8, the PC values obtained using NIOSH-IREP software v.5.8 might surpass the 50.00% compensability threshold. For this reason, a criteria was developed to select all the claims that might be affected as a result of this software upgrade. From the preliminary two analyses, it was recommended that all the claims from the NOCTS database, with PC values between 49.00% and 49.99% will be rerun on the NIOSH-IREP v.5.8 version, in order to determine if the PC values for these claims remain below the 50.00% threshold, or if the claims become compensable as a result of this new software upgrade. However, after taking into consideration the DOL concerns of possible exclusion of some of the affected claims, and the additional factor of including claims with multiple primary cancers, it was decided that all the claims from the NOCTS database, with PC values between 48.00% and 49.99% will be rerun on the NIOSH-IREP v.5.8 version.

Based on a query performed on the NOCTS database, it was determined that as of 12/06/2015, there were 117 non-compensable claims with PC values between 48.00%

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and 49.99%, which potentially might have the PC values increase above the 50.00% compensability threshold, when run on the NIOSH-IREP v.5.8 version. From these 117 claims, 53 of the cases are single cancer claims, and 64 have two or more primary cancers. Altogether, for these 117 claims, there are a total of 299 cancers that were necessary to be run on the NIOSH-IREP v.5.8 version. The NIOSH-IREP Enterprise Edition v.5.8 version, which is using 30 different runs with 10,000 iterations each, was used for each case in order to compute an Avg. PC value for each different cancer case. The same set of 30 random seeds that was originally used when each case was run on the NIOSH-IREP v.5.7.1 or an earlier version, was also used when the same case was rerun on the NIOSH-IREP v.5.8 version.

Table 2 shows the results of the evaluation of these 117 claims, including the original PC values obtained using NIOSH-IREP v.5.7.1 or an earlier version, the new PC values obtained using NIOSH-IREP v.5.8, and PC difference between the two IREP versions. The PC values corresponding to the claims with more than one cancer, were computed by combining the individual PC values from all the cancers associated with a claim, using the special formula for computing the combined PC value for a claim having multiple cancers.

None of the 117 non-compensable claims previously completed on NIOSH-IREP v.5.7.1 or an earlier version, become compensable as a result of running it on the NIOSH-IREP v.5.8 version.

Table 2: Summary of PC values obtained using IREP v.5.7.1 and IREP v.5.8.

Claim #	Number of cancers	Previously used IREP Version	PC from IREP v.5.7.1 or lower	PC from IREP v.5.8	PC difference (IREP v.5.8 - IREP v.5.7.1 or lower)
1	2	v.5.7ee	48.01	48.03	0.02
2	16	v.5.6ee	48.01	48.21	0.20
3	2	v.5.6ee	48.02	47.98	-0.04
4	1	v.5.5.2ee	48.02	48.06	0.04
5	4	v.5.6ee	48.05	48.15	0.10
6	1	v.5.7.1ee	48.08	47.98	-0.10
7	1	v.5.6ee	48.08	47.95	-0.13

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Claim #	Number of cancers	Previously used IREP Version	PC from IREP v.5.7.1 or lower	PC from IREP v.5.8	PC difference (IREP v.5.8 - IREP v.5.7.1 or lower)
8	4	v.5.7.1ee	48.09	47.98	-0.11
9	5	v.5.5.1ee	48.09	48.28	0.19
10	1	v.5.5.2ee	48.09	48.01	-0.08
11	1	v.5.5.2ee	48.12	47.90	-0.22
12	3	v.5.5.2ee	48.12	47.98	-0.14
13	1	v.5.6ee	48.15	48.21	0.06
14	2	v.5.6ee	48.17	48.00	-0.17
15	2	v.5.5.2ee	48.20	48.18	-0.02
16	1	v.5.6ee	48.21	48.25	0.04
17	2	v.5.6ee	48.23	47.97	-0.26
18	1	v.5.6ee	48.24	48.25	0.01
19	1	v.5.6ee	48.25	48.28	0.03
20	2	v.5.6ee	48.27	48.27	0.00
21	2	v.5.5.2ee	48.27	48.35	0.08
22	6	v.5.6ee	48.29	48.46	0.17
23	1	v.5.5.1ee	48.30	48.34	0.04
24	2	v.5.6ee	48.32	48.25	-0.07
25	1	v.5.7.1ee	48.33	48.46	0.13
26	5	v.5.7ee	48.33	48.30	-0.03
27	2	v.5.6ee	48.34	48.45	0.11
28	2	v.5.5.1ee	48.36	48.27	-0.09
29	3	v.5.7ee	48.36	48.42	0.06

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Claim #	Number of cancers	Previously used IREP Version	PC from IREP v.5.7.1 or lower	PC from IREP v.5.8	PC difference (IREP v.5.8 - IREP v.5.7.1 or lower)
30	1	v.5.6ee	48.38	48.58	0.20
31	1	v.5.5.1ee	48.39	48.39	0.00
32	2	v.5.5.1ee	48.40	48.64	0.24
33	1	v.5.5.1ee	48.41	48.48	0.07
34	1	v.5.5.3ee	48.42	48.57	0.15
35	1	v.5.5.2ee	48.42	48.59	0.17
36	1	v.5.5.2ee	48.42	48.30	-0.12
37	1	v.5.4ee	48.42	47.77	-0.65
38	2	v.5.7ee	48.43	48.45	0.02
39	2	v.5.6ee	48.43	48.51	0.08
40	1	v.5.5.1ee	48.46	48.82	0.36
41	2	v.5.7.1ee	48.48	48.67	0.19
42	2	v.5.5.1ee	48.49	48.64	0.15
43	1	v.5.5.3ee	48.50	48.78	0.28
44	1	v.5.6ee	48.58	48.81	0.23
45	9	v.5.7.1ee	48.60	48.48	-0.12
46	1	v.5.5.2ee	48.61	48.70	0.09
47	6	v.5.7.1ee	48.61	48.60	-0.01
48	3	v.5.6ee	48.66	48.73	0.07
49	1	v.5.5.2ee	48.66	48.68	0.02
50	3	v.5.5.2ee	48.69	48.93	0.24
51	2	v.5.6ee	48.70	48.57	-0.13

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Claim #	Number of cancers	Previously used IREP Version	PC from IREP v.5.7.1 or lower	PC from IREP v.5.8	PC difference (IREP v.5.8 - IREP v.5.7.1 or lower)
52	1	v.5.6ee	48.73	48.73	0.00
53	5	v.5.5.1ee	48.75	48.85	0.10
54	2	v.5.7ee	48.77	48.80	0.03
55	1	v.5.7ee	48.77	48.81	0.04
56	2	v.5.5.2ee	48.77	49.33	0.56
57	2	v.5.5.2ee	48.79	48.72	-0.07
58	2	v.5.5.1ee	48.80	48.87	0.07
59	1	v.5.6ee	48.81	49.08	0.27
60	1	v.5.6ee	48.82	48.71	-0.11
61	6	v.5.6ee	48.83	49.00	0.17
62	2	v.5.6ee	48.83	48.87	0.04
63	3	v.5.7.1ee	48.84	48.92	0.08
64	1	v.5.6ee	48.85	49.04	0.19
65	1	v.5.5.2ee	48.87	48.73	-0.14
66	1	v.5.6ee	48.87	48.79	-0.08
67	1	v.5.5.3ee	48.87	48.94	0.07
68	4	v.5.7ee	48.87	48.84	-0.03
69	1	v.5.5.3ee	48.88	49.03	0.15
70	1	v.5.5.2ee	48.89	48.79	-0.10
71	4	v.5.5.2ee	48.94	48.80	-0.14
72	1	v.5.7.1ee	49.02	48.84	-0.18
73	2	v.5.4ee	49.03	48.88	-0.15

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Claim #	Number of cancers	Previously used IREP Version	PC from IREP v.5.7.1 or lower	PC from IREP v.5.8	PC difference (IREP v.5.8 - IREP v.5.7.1 or lower)
74	9	v.5.6ee	49.04	49.20	0.16
75	1	v.5.5.1ee	49.05	49.14	0.09
76	2	v.5.7ee	49.06	48.95	-0.11
77	9	v.5.6ee	49.07	49.08	0.01
78	1	v.5.5.1ee	49.08	49.09	0.01
79	1	v.5.5.2ee	49.08	49.11	0.03
80	13	v.5.6ee	49.09	49.10	0.01
81	3	v.5.5.2ee	49.09	48.84	-0.25
82	4	v.5.5.1ee	49.10	49.05	-0.05
83	12	v.5.6ee	49.10	48.95	-0.15
84	2	v.5.7.1ee	49.13	49.02	-0.11
85	1	v.5.6ee	49.13	49.03	-0.10
86	2	v.5.6ee	49.14	49.11	-0.03
87	2	v.5.7ee	49.17	49.16	-0.01
88	1	v.5.5.1ee	49.18	48.88	-0.30
89	4	v.5.6ee	49.20	49.12	-0.08
90	2	v.5.6ee	49.21	49.34	0.13
91	1	v.5.5.2ee	49.23	49.20	-0.03
92	9	v.5.5.2ee	49.30	49.27	-0.03
93	1	v.5.6ee	49.36	49.37	0.01
94	1	v.5.6ee	49.36	49.36	0.00
95	1	v.5.5.2ee	49.38	49.43	0.05

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Claim #	Number of cancers	Previously used IREP Version	PC from IREP v.5.7.1 or lower	PC from IREP v.5.8	PC difference (IREP v.5.8 - IREP v.5.7.1 or lower)
96	3	v.5.7.1ee	49.39	49.28	-0.11
97	3	v.5.5.2ee	49.41	49.36	-0.05
98	1	v.5.5.1ee	49.44	48.95	-0.49
99	3	v.5.6ee	49.52	49.42	-0.10
100	1	v.5.5.1ee	49.57	49.81	0.24
101	1	v.5.5.1ee	49.61	49.81	0.20
102	1	v.5.7.1ee	49.65	49.90	0.25
103	2	v.5.6ee	49.66	49.82	0.16
104	2	v.5.6ee	49.68	49.75	0.07
105	4	v.5.7ee	49.72	49.52	-0.20
106	2	v.5.5.1ee	49.73	49.44	-0.29
107	1	v.5.7ee	49.73	49.92	0.19
108	1	v.5.7ee	49.75	49.79	0.04
109	8	v.5.7.1ee	49.75	49.76	0.01
110	5	v.5.6ee	49.76	49.75	-0.01
111	1	v.5.5.2ee	49.79	49.02	-0.77
112	1	v.5.5.2ee	49.81	49.87	0.06
113	1	v.5.5.1ee	49.84	49.75	-0.09
114	2	v.5.5.2ee	49.84	49.82	-0.02
115	2	v.5.6ee	49.86	49.97	0.11
116	1	v.5.5.1ee	49.87	49.66	-0.21
117	4	v.5.6ee	49.90	49.96	0.06

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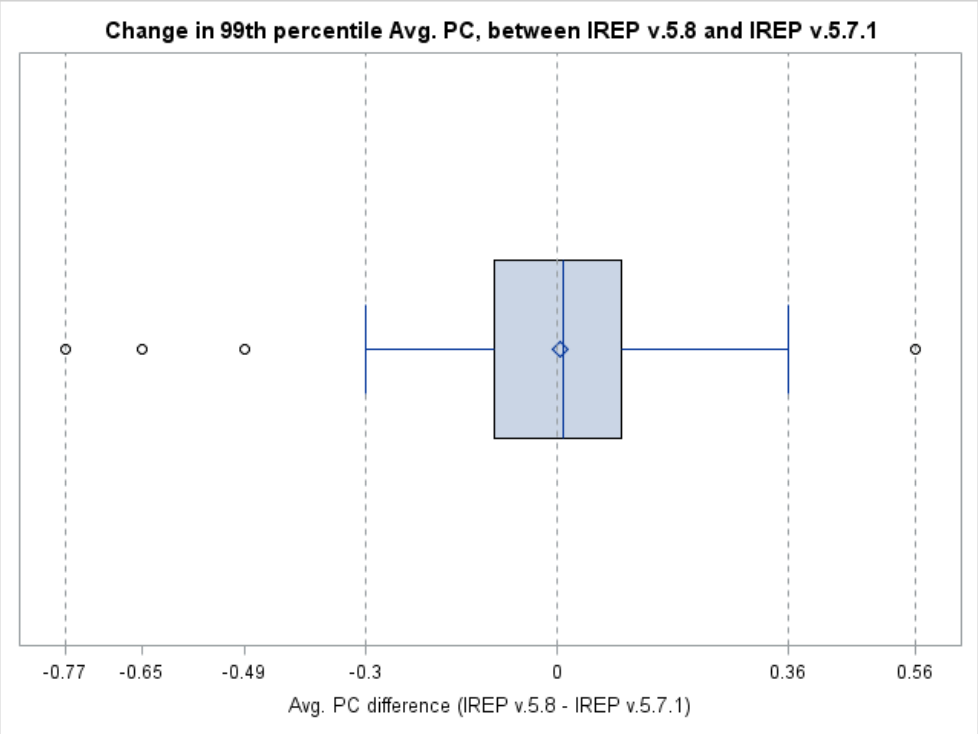
The differences in the Avg. PC values between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, for all the 117 claims, range from -0.77 to 0.56, with a mean value of 0, a median of 0.01, and a standard deviation of 0.18. A boxplot for the differences in the Avg. PC values, between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, is shown in Figure 1.

Figure 1: Boxplot with differences in Avg. PC values, between IREP v.5.8 and IREP v.5.7.1, for the 117 claims.



The extreme value of -0.77, -0.65, -0.49, and 0.56 were obtained for claims with Nervous System, Gallbladder, Urinary organs (excluding bladder), and Bladder cancers. For all the other 113 claims, the difference in the PC values between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, range from -0.30 to 0.36.

A density plot for the differences in the Avg. PC values between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, for the 117 claims, is shown in Figure 2. The distribution of the differences in the Avg. PC values between NIOSH-IREP using ADE 4.5 versus NIOSH-IREP using ADE 3.0 is approximately normally distributed around 0, with a standard deviation of 0.18.

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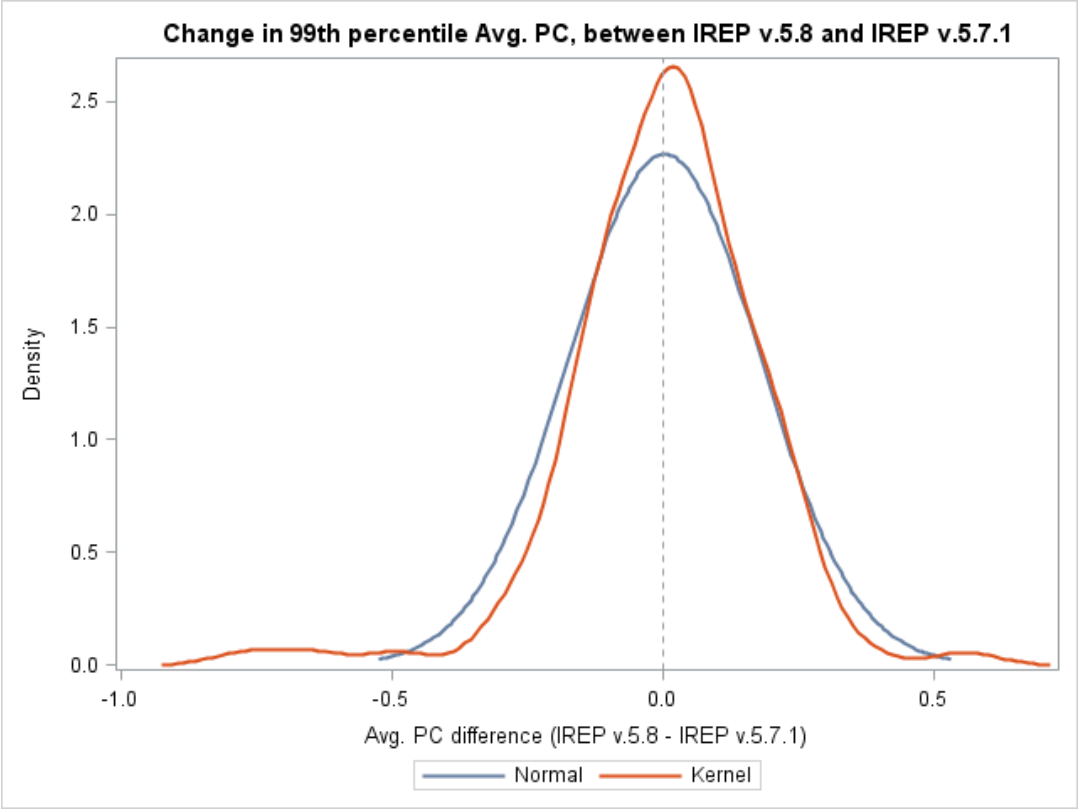
Figure 2: Density plot for the differences in Avg. PC values, between IREP v.5.8 and IREP v.5.7.1, for the 117 claims.



As an additional analysis, the differences in the Avg. PC values between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1 for all the 299 cancers associated with the 117 claims, are also summarized. The differences in the Avg. PC values between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, for all the 299 cancers, range from -0.77 to 0.41, with a mean value of 0, a median of 0.01, and a standard deviation of 0.12. The majority of the cancers correspond to the IREP skin cancer models (Non-melanoma skin-Basal Cell, and Non-melanoma skin-Squamous Cell), which had lower PC values on the NIOSH-IREP v.5.7.1 version or earlier versions, and also had much smaller changes in their PC values when they were rerun on the NIOSH-IREP v.5.8 version. A boxplot for the differences in the Avg. PC values, between NIOSH-IREP v.5.8 versus NIOSH-IREP v.5.7.1, is shown in Figure 3. The distribution of the differences in PC values for the 299 cancers is narrower than the distribution of the differences in PC values for the 117 claims, with

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90% of the values ranging between -0.2 and 0.2, and 54% of the values ranging between -0.05 and 0.05.

Figure 3: Boxplot with differences in Avg. PC values, between IREP v.5.8 and IREP v.5.7.1, for the 299 individual cancers.

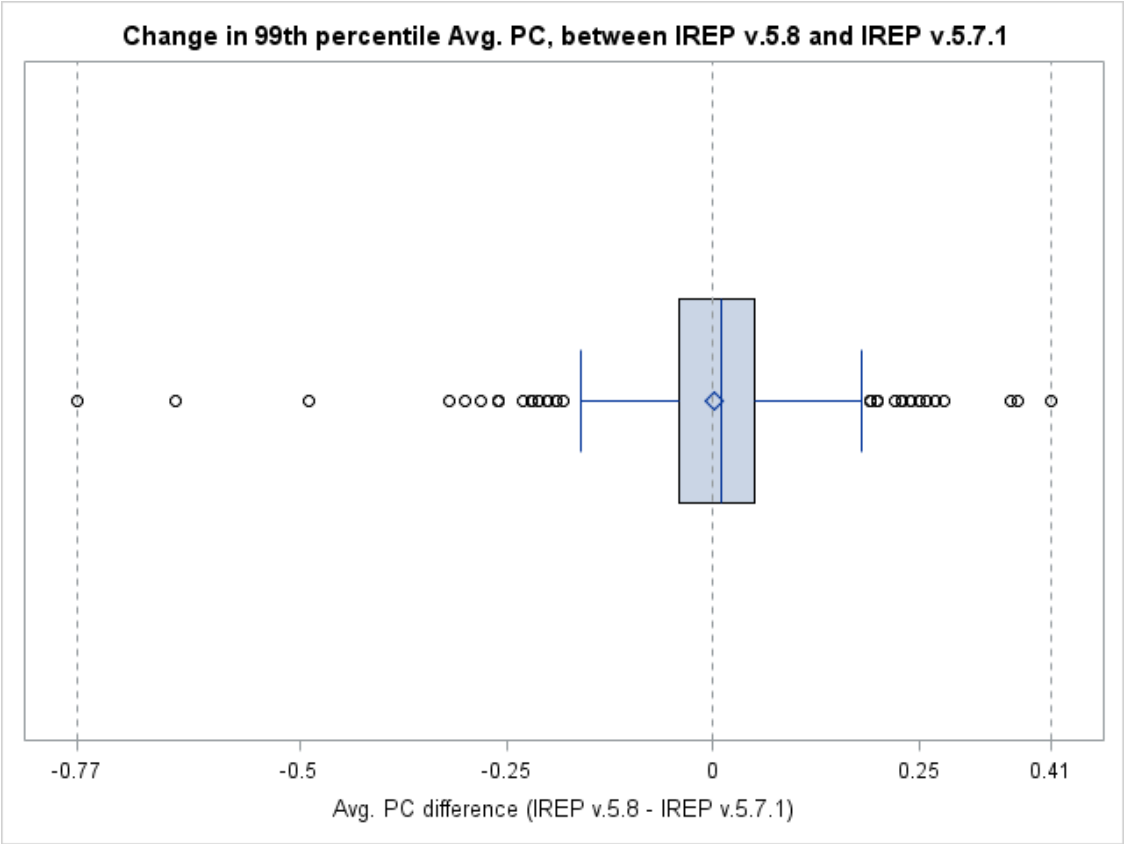

Table 3 shows the summary statistics for the final analysis, including the 117 claims with PC values between 48.00% and 49.99%, and also for the 299 cancers associated with the 117 claims.

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Analysis of NIOSH-IREP v.5.8 Upgrade
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Table 3: Summary statistics for the differences in Avg. PC values between IREP v.5.8 and IREP v.5.7.1

Final evaluation	N	Min	Median	Mean	Max	Std. Dev.
All 117 claims, with PC values between 48.00% and 49.99%	117	-0.77	0.01	0.00	0.56	0.18
All 299 cancers, associated with the 117 claims, having PC values between 48.00% and 49.99%	299	-0.77	0.01	0.00	0.41	0.12

Conclusion

The NIOSH-IREP software was upgraded from version v.5.7.1 to version v.5.8 on December 16, 2015. The NIOSH-IREP v.5.8 version is able to handle any claim up to a maximum 1,000 rows of exposure information, and offers speed increases which result in claims being calculated up to five times faster than the claims being run on the previous NIOSH-IREP v.5.7.1 software. Starting on 12/06/2015, all the new claims are run using the NIOSH-IREP software v.5.8. All the non-compensable claims from the NOCTS database, with a PC value between 48.00% and 49.99% as of 12/06/2015, were selected to be rerun on the NIOSH-IREP v.5.8 version. None of the 117 non-compensable claims previously completed on NIOSH-IREP v.5.7.1 or an earlier version, and with a PC value between 48.00% and 49.99% as of 12/06/2015, become compensable as a result of running it on the NIOSH-IREP v.5.8.