IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MICHELLE MCMUNN, Personal Representative of the Estate of EVA MYERS, et al., Plaintiffs,	)	
v.	)	2:10cv143
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

JESSI ANN CASELLA, et al., Plaintiffs,	)	
v.	)	2:10cv368
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

MICHAEL P. HUTH, et al., Plaintiffs,	)	
v.	)	2:10cv650
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

LINDA W. DILIK, Plaintiff,	)	
v.	)	2:10cv728
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

BONNIE AIKENS, et al.,	)	
Plaintiffs,	)	
v.	)	2:10cv744
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

PATRICIA ALTIMIRE, et al.,	)	
Plaintiffs,	)	
v.	)	2:10cv908
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

MARCIA BAUSTERT, et al.,	)	
Plaintiffs,	)	
v.	)	2:11cv898
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

SANDRA L. AMENT, et al.,	)	
Plaintiffs,	)	
v.	)	2:11cv1381
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

ELIZABETH MITCHESON, et al.,	)	
Plaintiffs,	)	
v.	)	2:12cv1221
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

KAREN L. SKROUPA, as personal representative of HOWARD D. SKROUPA, deceased, Plaintiff,	)	
v.	)	2:12cv1459
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

HEATHER LORRAINE BAYNAR, et al., Plaintiffs,	)	
v.	)	2:10cv1736
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

MEMORANDUM OPINION

February 27, 2014

I. INTRODUCTION

The above captioned cases were referred to United States Magistrate Judge Robert Mitchell for pretrial proceedings in accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1), and the Local Rules of Court for Magistrate Judges. In these actions, more than seventy-five (75) Plaintiffs allege that Defendants, Babcock & Wilcox Power Generation Group, Inc., B&W Technical Services, Inc. ("B&W") and Atlantic Richfield Co. ("ARC")(together "Defendants"), as successors in interest to Nuclear Materials Corporation ("NUMEC"), are responsible for the release of radioactive uranium from a nuclear processing facility located in Apollo, Pennsylvania and operated from approximately 1953 to 1983. Plaintiffs further allege that inhalation of radioactive uranium from the facility caused the Plaintiffs to develop cancer. Plaintiffs assert jurisdiction under the Price-Anderson Act (the "PAA"), 42 U.S.C. § 2210(n)(2), and the Atomic Energy Act (the "AEA"), 42 U.S.C. § 2011.

The PAA, as amended in 1988, created a federal cause of action for "public liability actions," which is defined as "any suit asserting public liability." 42 U.S.C. § 2014(h). "Public liability" is defined as "any legal liability arising out of or resulting from a nuclear incident or precautionary evacuation," except for certain claims covered by workers' compensation, incurred in wartime or that involve the licensed property where the nuclear incident occurs. 42 U.S.C. § 2104(w). *See In re TMI Litig.*, 193 F.3d 613, 625 n.9 (3d Cir. Pa. 1999).

In order to prove personal injuries caused by the release of radiation, the Third Circuit has previously held that plaintiffs must establish that:

> (1) the defendants released radiation into the environment in excess of the levels permitted by federal regulations in effect in 1979, i.e., 0.5 rems (500 mrems) or 5 mSv; (2) the plaintiffs were exposed to this radiation (although not necessarily at levels prohibited by those regulations); (3) the plaintiffs have injuries; and (4) radiation was the cause of those injuries. *See In re TMI*, 67 F.3d 1103, 1119 (3d Cir. 1995), *cert. denied*, 516 U.S. 1154 (1996). [The Third Circuit] also held that the "exposure element requires that plaintiffs demonstrate they have been exposed to a greater extent than anyone else, *i.e.*, that their exposure levels exceeded the normal background level." *Id.* (citation and internal quotations omitted).

In re TMI Litig., 193 F.3d at 659. By Order entered September 12, 2012, Plaintiffs' claims were limited to theories of exposure based upon the inhalation of enriched uranium released from the Apollo facility during its period of operation.

The parties filed eight (8) motions to exclude expert testimony, opinions and or reports pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Specifically, Defendants moved to exclude the opinions of Howard Hu, M.D., James Melius, M.D., Bernd Franke, Joseph Ring, Ph.D. and Donal Kirwan, and the Plaintiffs moved to exclude John Till, Ph.D., Christopher Whipple, Ph.D., Stanley Hayes, Fred A. Mettler, M.D. and John D. Boice, Jr. Following and two-day hearing and post-hearing briefing, the Magistrate Judge filed a Report and Recommendation ("R&R") on July 12, 2013, which recommended that: (1) Defendants'

Motion to Exclude Expert Opinions of Mr. Bernd Franke and Joseph Ring, Ph.D., be granted; (2) Defendants' Motion to Exclude Expert Testimony and Opinions of Donal Kirwan be denied; (3) Defendants' Motion to Exclude Expert Opinions of Dr. Howard Hu be granted; (4) Defendants' Motion to Exclude Testimony of James Melius be granted; (5) Plaintiffs' Motion to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Expert John E. Till Ph.D. be denied; (6) Plaintiffs' Motion to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Experts Dr. Christopher Whipple and Stanley Hayes be denied; (7) Plaintiffs' Motion to Exclude Testimony and Report of Fred A. Mettler, Jr., M.D., M.P.H. be denied; and (8) Plaintiffs' Motion to Exclude Testimony and Studies of Dr. John D. Boice, Jr. be denied. Magistrate Judge Mitchell further recommended that, if this Court adopts the R&R, Plaintiffs be given 21 days from the date of the order to show cause why summary judgment should not be entered in Defendants' favor.

The Plaintiffs have filed Objections to Magistrate Judge Mitchell's R&R, the parties have filed briefs in support of their positions, and the matter is now before the Court.

II. STANDARD OF REVIEW

The Federal Magistrates Act provides two separate standards of judicial review of orders on matters referred to magistrate judges. *See* 28 U.S.C. § 636(b)(1). Under § 636(b)(1)(A), the Act permits district courts to "designate a magistrate judge to hear and determine any pretrial matters before the court, except . . ." 28 U.S.C. § 636(b)(1)(A). This Court reviews orders on matters referred to magistrate judges under subparagraph (A), generally described as "nondispositive", under a "clearly erroneous or contrary to law" standard. *See* 28 U.S.C. § 636(b)(1)(A); FED. R. CIV. P 72 (a); *see also Haines v. Liggett Group, Inc.*, 975 F.2d 81, 91-92

(3d Cir. 1992).

A magistrate judge's decision is clearly erroneous "when, although there may be some evidence to support it, the reviewing court, after considering the entirety of the evidence, is left with the definite and firm conviction that a mistake has been committed." *United States v. Gypsum Co.*, 333 U.S. 364, 395 (1948); *see also Kounelis v. Sherrer*, 529 F. Supp. 2d 503, 518 (D.N.J. 2008); *Lo Bosco v. Kure Engineering Ltd.*, 891 F. Supp. 1035, 1037 (D.N.J. 1995). A finding is contrary to law if the magistrate judge has misinterpreted or misapplied applicable law. *Kounelis v. Sherrer*, 529 F. Supp. 2d at 518. The burden of demonstrating clear error rests with the appealing party. *Id.*

On review of matters arising under § 636(b)(1)(A), the court is not permitted to receive further evidence; it is bound by the clearly erroneous rule in reviewing questions of fact. *Haines v. Liggett Group, Inc.*, 975 F.2d at 91. Further, under the clearly erroneous standard, a reviewing court will not reverse the magistrate judge's determination "even if the court might have decided the matter differently." *Cooley v. Merski*, 2008 U.S. Dist. LEXIS 50271, *3 (W.D. Pa. June 26, 2008) (citing *Cardona v. General Motors Corp.*, 942 F. Supp. 968, 971 (D.N.J. 1996)).

When a district court considers "written objections" to the "proposed findings and recommendations" of the magistrate judge in dispositive matters, however, the district court is permitted to make a *de novo* determination of the proposed findings and recommendations, may accept, reject or modify, in whole or in part, the findings and recommendations, and "may also receive further evidence." *See* 28 U.S.C. § 636(b)(1)(B) & (C), FED. R. CIV. P 72 (b); *see also Haines v. Liggett Group, Inc.*, 975 F.2d at 91.

Generally, discovery orders are treated as nondispositive matters. *Haines v. Liggett Group, Inc.*, 975 F.2d at 92 (holding that "the proper standard for review for discovery orders is

the 'clearly erroneous or contrary to law' standard."); *In re Gabapentin Patent Lit.*, 312 F.Supp.2d 653, 662 (D.N.J. 2004). A ruling on a motion to preclude expert testimony, therefore, is a nondispositive disposition under 28 U.S.C. § 636(b)(1)(A). *See Dalton v. McCourt Elec., LLC*, 2013 U.S. Dist. LEXIS 176582 *3 n.1 (E.D. Pa. Dec. 17, 2013) (citing *Stepney v. Gilliard*, 2006 U.S. Dist. LEXIS 53722 (D.N.J. Aug. 3, 2006)). Moreover, a magistrate judge's ruling on discovery issues is accorded particular deference. *Durkin v. Wabash Nat'l*, 2013 U.S. Dist. LEXIS 140568, *6 (D.N.J. Sept. 30, 2013); *Stayinfront, Inc. v. Tobin*, 2006 U.S. Dist. LEXIS 80498, *6 (D.N.J. Nov. 3, 2006).

It is clear in this instance, that Plaintiffs' *Daubert* motions are nondispositive, therefore, the Court will apply the "clearly erroneous or contrary to law" standard. With regard to Defendants' motions, however, adoption of Magistrate Mitchell's recommendations is case-dispositive, and shall be reviewed *de novo*.

III. DISCUSSION

The motions before the Court implicate the admissibility standard for expert witnesses under Rule 702 of the Federal Rules of Evidence as elucidated by the Supreme Court in *Daubert*. In *Daubert*, the Supreme Court set forth parameters for determining when proffered expert testimony can be admitted into evidence. The Court held:

> Proposed testimony must be supported by appropriate validation -- *i.e.,* "good grounds," based on what is known. In short, the requirement that an expert's testimony pertaining to "scientific knowledge" establishes a standard of evidentiary reliability.

Daubert, 509 U.S. at 590. The Court concluded that Rule 702 "clearly contemplates some degree of regulation of the subjects about which an expert may testify." 509 U.S. at 589. Thus, the Court established a "gatekeeping role for the judge." *Id.* at 597. The Court wrote:

> Faced with a proffer of expert scientific testimony, . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Id. at 592-593. Moreover, the Third Circuit has established that Rule 702 includes "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability and fit." *United States v. Mathis*, 264 F.3d 321, 335 (3d Cir. 2001); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

First, the witness must be a qualified expert, meaning that the witness must possess specialized expertise. *Feit v. Great-West Life & Annunity Ins. Co*., 460 F. Supp. 2d 632, 636 (D.N.J. 2006). Courts have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert. *In re TMI Litig.*, 193 F.3d 613, 664 (3d Cir. 1999).

Second, Rule 702 requires that the testimony be reliable. The Supreme Court instructed that an "expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation;' the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995) (quoting *Daubert*, 509 U.S. at 590)). The Court emphasized, however, that the "focus . . . must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595. The issue, therefore, is whether the evidence should be excluded because the flaw is large enough that the expert lacks good grounds for his or her conclusion. *In re Paoli R.R Yard PCB Litigation*, 35 F.3d at 746. Further, an "expert's testimony must be accompanied by a sufficient factual foundation before it can be submitted to the jury." *Elcock v. Kmart Corp.*, 233 F.3d at 754.

Daubert identified several factors that a district court should take into account in evaluating whether a particular scientific methodology is reliable. *In re Paoli R.R Yard PCB Litigation*, 35 F.3d at 742. The factors that *Daubert* and the Third Circuit have declared important include: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *In re Paoli R.R Yard PCB Litigation*, 35 F.3d at 742 n.8. *See also Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000), *cert. denied*, 532 U.S. 921 (2001); *Elcock v. Kmart Corp.*, 233 F.3d at 745-746; *In re TMI Litig.*, 193 F.3d 613, 664 (3d Cir. 1999).

Daubert makes clear that these factors do not constitute a "definitive checklist or test." *Daubert*, 509 U.S. at 593. A court's gatekeeping inquiry must be "tied to the facts" of a particular "case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999). "Whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine." *Id.* at 153.

Moreover, the court's role as a gatekeeper "is not intended to serve as a replacement for the adversary system." *See Crowley v. Chait*, 322 F. Supp. 2d 530, 536 (D. N. J. 2004) quoting FED. R. EVID. 702, Advisory Committee's Note. The *Daubert* Court recognized that jurors will have the capacity to distinguish "junk science" from the real thing. Accordingly, where an expert is expected to deliver "shaky" testimony, admission of the testimony may still be proper because "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the

burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. The Third Circuit further commented on the reliability notion of *Daubert*, stating:

> The evidentiary requirement of reliability is lower than the merits standard of correctness. Further, a court may determine that "good grounds" exist for the expert opinion to be offered, even though the judge may believe "better grounds" exist for an alternate conclusion or that a somewhat flawed methodology, if fixed, would lead to a different conclusion.

Allstate Ins. Co. v. Hamilton Beach/Proctor-Silex, Inc., 2008 U.S. Dist. LEXIS 63355 *12 (W.D. Pa. Aug. 19, 2008)(citing *In re Paoli R.R Yard PCB Litigation*, 35 F.3d at 744).

Finally, the expert's testimony must "fit" or "be relevant for the purposes of the case and must assist the trier of fact." *Calhoun v. Yamaha Motor Corp*., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003)). The touchstone for admissibility under Rule 702, is helpfulness to the trier of fact. FED. R. EVID. 702 (a). However, while the standard for fitness is higher than bare relevance, it is not that high. *In re Paoli R.R Yard PCB Litigation*, 35 F.3d at 745. In order to assist the trier of fact in understanding the evidence or in determining an issue of fact, the scientific or other specialized knowledge must be logically connected to the questions at issue in the case. *Id.* at 742-743. In contrast, expert testimony based on assumptions that lack any factual support in the record are properly excluded. *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002); *Elcock v. Kmart Corp.*, 233 F.3d at 756 n.13.

The proponent of the expert testimony bears the burden of establishing the reliability and admissibility of the expert's testimony by a preponderance of the evidence. *See Daubert*, 509 U.S. at 593 n. 10; *In re TMI Litig.*, 193 F.3d at 663. Moreover, Rule 702 embodies a liberal policy of admissibility. *Pineda v. Ford Motor Co.,* 520 F.3d 237, 243 (3d Cir. 2008); *In re Paoli*

R.R. Yard PCB Litig., 916 F.2d 829, 857 (3d Cir. 1990).

In the motions at issue, the qualifications of the experts are not disputed. The parties argue, however, that the testimony of the many experts is not based on reliable methodology and will not assist the trier of fact.

A. Plaintiffs' Experts

1. Howard Hu, M.D., M.P.H., Sc.D.

Dr. Hu, Plaintiffs' general causation expert, is a physician and an environmental and occupational epidemiologist who holds degrees as a Doctor of Science and Master of Public Health. In his report, Dr. Hu opines as follows:

(1) The Apollo nuclear plant emitted a mixture of radionuclides including highly enriched uranium, thorium and plutonium[1]. Radionuclides are known to increase the risk of developing cancer based on their property of emitting ionizing radiation in the form mainly of alpha and beta particles and their ability to be absorbed by the human body through inhalation and/or ingestion and widely distribute to tissues throughout the body.

(2) The ability of the specific radionuclides associated with the Apollo nuclear plant (highly enriched uranium, thorium and plutonium) to cause cancer is supported by their well-known emission of ionizing radiation as well as specific experimental and epidemiologic studies. The ionizing radiation from these radionuclides could be expected to have increased the risk of any of the cancers alleged by the Plaintiffs in the instant actions.

3. With regard to individuals who lived, worked, or otherwise spent a significant amount of time within the likely exposure area and who subsequently developed a cancer associated with ionizing radiation, it would be reasonable to conclude that ionizing radiation exposure from the emission of radionuclides from the Apollo nuclear plant may have constituted a substantial contributing factor towards the causation of that cancer.

4. The results of the studies conducted by Dr. John Boice and the Pennsylvania Department of Health ("PDH") do not contradict Dr. Hu's opinions because such studies are subject to a large number of limitations

[1] As stated previously, Plaintiffs' claims are limited to theories of exposure based upon the inhalation of enriched uranium released from the Apollo facility during its period of operation.

> related to the general methodologic issues of ecologic epidemiology studies as well as specific additional limitations and incorrect assumptions related to the research designs of these same studies.

Meier Declaration (Document No. 212), Exhibit C, Report of Dr. Hu, p. 14.

Magistrate Judge Mitchell concluded that Dr. Hu's opinions failed to satisfy the *Daubert* requirements and must be excluded. Specifically, Magistrate Judge Mitchell found: (1) Dr. Hu's contention that "radiation is radiation," and his willingness to base his causation conclusion on any study that demonstrates an association between any type of ionizing radiation and a particular cancer is unsupported by scientific sources; (2) Dr. Hu's hypothesis that uranium causes cancer throughout the body cannot be tested using the Bradford Hill criteria,[2] the methodology that Dr. Hu called the "gold standard" for determining causation; and (3) it is unreasonable for Dr. Hu to rely on general statements in a report by the International Agency for Research on Cancer (the "IARC") that "internalized radionuclides that emit alpha particles and beta particles are carcinogenic to humans" to support his conclusion that natural uranium exposure caused cancer in the Plaintiffs, when the IARC found that the degree of evidence of carcinogenicity of uranium and its decay product, inhalation of ore dust containing uranium-234, utanium-235 and uranium-238 was "limited" in animals and "inadequate" in humans. *See* R&R pp. 38-39.

Although the Supreme Court in *Daubert* stressed that trial courts focus on principles and methodology instead of the conclusions generated therefrom, the Court subsequently clarified

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[2] Sir Austin Bradford Hill published a method for addressing general causation that involves nine criteria of associations that scientists should consider before deciding that the most likely interpretation of the association is causation: (1) Strength of Association; (2) Consistency; (3) Specificity; (4) Temporality; (5) Dose-response or biologic gradient; (6) Biologic plausibility; (7) Coherence; (8) Experimental evidence; and (9) Analogy. The "Bradford Hill criteria" are commonly used by epidemiologists today to render general causation determinations. Mettler Declaration (Document No. 210) ¶ 16.

that this focus "need not completely pretermit judicial consideration of an expert's conclusions." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). The Court further explained that "conclusions and methodology are not entirely distinct from one another" and "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. at 146. This does not mean, however, that trial courts are empowered "to determine which of several competing scientific theories has the best provenance." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d at 85. "*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct." *Id.* The proponent of the evidence must show only that "the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *Id.*

Because another explanation may be more correct, such explanation is not a sufficient basis for excluding Dr. Hu's testimony. "Lack of certainty is not, for a qualified expert, the same thing as guesswork." *Primiano v. Cook*, 2010 U.S. App. LEXIS 8859, 2010 WL 1660303, *5 (9th Cir. Apr. 27, 2010). Moreover, as the Court of Appeals for the First Circuit recognized, "[t]here is an important difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion." *Milward v. Acuity Specialty Prods. Group*, 639 F.3d 11, 22 (1st Cir. 2011). In this instance, therefore, the Court finds that Dr. Hu's opinions have met the pedestrian standards required for reliability and fit, as they are based on scientifically sound methods and procedures, as opposed to "subjective belief or unsupported speculation." Dr. Hu has demonstrated "good grounds" for his opinion, therefore, "[a]ny dispute between the parties about the strength of the evidence in this case should be resolved by the

jury." *Thomas & Betts Corp. v. Richards Mfg. Co.*, 342 Fed. Appx. 754, 761 (3d Cir. 2009) (quoting *Pineda v. Ford Motor Co.,* 520 F.3d at 249)).

In discussing his methodology, Dr. Hu explained that, after reading the reports describing the exposure that likely occurred to residents in the community surrounding the Apollo plant, he determined:

> The clear, most important exposure of interest . . . was the enriched uranium, because it's an alpha emitter and because it pro rata . . . is more biologically active than natural uranium. . . . I went back to the literature to update my understanding of the carcinogenic potential of enriched uranium, recognizing quickly, of course, that it's an alpha particle emitter and that alpha particles are undoubtedly known to be carcinogenic. And then, doing a review of studies on the epidemiology surrounding uranium, very mindful of how, in fact, it has been known that the research base is relatively constrained. . . . This was pointed [out in a 2008 review in Health Physics] one of the major journals in science that reviewed the studies on uranium and workers and noted these very significant deficiencies in the research base that are important . . .

Daubert Hearing, May 1, 2013, pp. 108-109. Recognizing that "there are quite a few studies of uranium workers," Dr. Hu indicated that such studies:

> are flawed. They have these inherent weaknesses because they did not have good measures of internal dose. . . to be carcinogenic, [uranium] has to be absorbed into the body and travel to various organs. Well, that means that simply having a classification of whether a worker was in the uranium industry or not is much too imprecise to actually understand if they . . . actually had a dose of internal uranium, particularly [because various] industrial controls were used.

Id. at 109-110. Dr. Hu indicated that there were very few studies that had good actual measurements of internal dose. *Id.* at 110. Dr. Hu also testified regarding a 2008 review of twenty-three (23) epidemiological studies, eighteen (18) cohort studies and five (5) nested case-control studies which concluded that the study provided limited evidence of a relationship between site-specific cancer mortality and internal exposure to uranium and mixed fission products. The authors identified three main limitations common to such studies: limited statistical power, low radiation doses, and inaccurate exposure assessment. *Id*. at 112.

Dr. Hu determined that the studies on uranium workers were inconclusive with regard to the carcinogenic potential of exposure to enriched uranium, and relied upon the body of epidemiology on ionizing radiation to opine that exposure to highly enriched uranium can cause various cancers in humans[3]. Dr. Hu's conclusion is supported by the National Research Council's Committee on the Biological Effects of Ionizing Radiation ("BEIR VII") which stated:

> Because of uncertainty in occupational risk estimates and the fact that errors in doses have not formally been taken into account in these studies, the committee has concluded that the occupational studies are currently not suitable for the projection of population based risks. These studies, however, provide a comparison to the risk estimates derived from the atomic bomb survivors.

See BEIR VII at 206. Dr. Hu's conclusion is further supported by the Third Circuit's ruling in *TMI*, stating:

> Although there is scientific consensus that ionizing radiation can cause cancer, ionizing radiation is not currently known to leave a tell-tale marker in those cells which subsequently become malignant. Medical examinations and laboratory tests can determine the type and extent of a cancer, suggest an optimal treatment, and provide a likely prognosis, but they rarely (if ever) provide definite information as to its cause. Consequently, medical evaluation, by itself, can neither prove nor disprove that a specific malignancy was caused by a specific radiation exposure. **Therefore, the primary basis to link specific cancers with specific radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation. In other words, causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation.**

In re TMI Litig., 193 F.3d 613, 643 (3d Cir. 1999) (internal citation omitted) (emphasis added).

The Court is unable to find it scientifically unreliable, or unreasonable, to determine the existence of a risk of cancer for a particular radionuclide by reference to the body of science establishing the carcinogenicity of ionizing radiation. In 2001, the IARC concluded

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[3] The defendants rely on *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814 (W.D. Tex. 2005) to support their argument to exclude Dr. Hu's expert opinion. *Cano*, however, has no precedential value in this Court, and its holding is not reconcilable with the Third Circuit's holding in *In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999).

that"[i]nternalized radionuclides that emit α-particles are carcinogenic to humans (Group I)." IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 78 Ionizing Radiation, Part 2: *Some Internally Deposited Radionuclides*, 2001 IARC Press, p. 479. The IARC reiterated its assessment with regard to alpha particles in 2012. *See* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100D, *Radiation: a Review on Human Carcinogens*, 2012 IARC Press, p. 275. Also noted by the IARC in the 2012 monograph, was the limited evidence of a positive association on studies focused exclusively with uranium, although such studies may not be reliable to the extent causation claims could be made based solely upon such limited evidence. *Id.* at 25. The IARC, however, found the evidence sufficient to mandate a classification of uranium as "probably carcinogenic to humans." *Id.* at 28.

In explaining the IARC 2012 report and its consistency with his opinions, Dr. Hu further explained:

> [The report] defined limited evidence of carcinogenicity, sufficient evidence of carcinogenicity, inadequate evidence of carcinogenicity, and my opinions are aligned with their definition. . . [T]he definition of limited evidence of carcinogenicity is the data suggests a carcinogenic effect, but are limited from making a definitive evaluation because, and then they list several of the reasons why they would categorize something as limited evidence.
>
> But again, we're in the realm of science wanting to make a definitive evaluation. Here we have a substance that's a known alpha emitter. They've already made a definitive statement on that. And in my view, coupled that with the evidence that exists, limited as it is, I feel very comfortable concluding that more likely than not enriched uranium, such as that exposed to residents around Apollo, is carcinogenic.

Daubert Hearing, May 1, 2013, pp. 113-114.

Further, Defendants' contention that Dr. Hu's "weight of the evidence" methodology disregards the "overwhelming" evidence specific to uranium, in favor of evidence regarding "ionizing radiation" and alpha particle emitters is unconvincing. The "overwhelming" evidence specific to studies of uranium workers has been found to be limited and/or inadequate with

regard to the carcinogenic potential of exposure to enriched uranium. Moreover, reliance on the application of general ionizing radiation epidemiology to specific radionuclide exposures is supported by the Third Circuit's opinion in *TMI*.

The Court also finds Dr. Hu's testimony regarding the Bradford Hill criteria to be reasonable. Dr. Hu testified that:

> highly enriched uranium is a well-known emitter of the alpha particles. The International Agency for Research on Cancer had done an exhaustive review of the carcinogenic potential of alpha particles, including using the Bradford Hill criteria, although, they didn't specifically say so, and concluded that alpha particles cause cancer. So, in my view, I incorporated the Bradford Hill criteria in using the IARC conclusion that alpha particles cause cancer in my determination of the carcinogenic potential of uranium.

Daubert Hearing, May 1, 2013, p. 58. There is scientific consensus that alpha particles, from whatever source, can cause the biological changes that result in the development of cancer.

The alleged flaws in Dr. Hu's methodology go to the weight of Dr. Hu's opinion, not its admissibility. There is a difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion. Moreover, because reasonable scientific minds can differ on the methodologies discussed, the motion to exclude the opinion of Dr. Hu will be denied.

2. James Melius, M.D., DRPH[4]

Dr. Melius was retained by Plaintiffs' as their specific causation expert. Dr. Melius is a

[4] In a prior case captioned *Hall v. Babcock & Wilcox Co.*, Civil Action No. 94-951, in which over 500 plaintiffs sued B&W and ARC alleging personal injury resulting from the emission of ionizing radiation from the Apollo and Parks facilities, Dr. Melius, acting as a causation expert for plaintiffs, performed a differential diagnosis methodology to opine that exposure to the ionizing radiation was a substantial contributing factor in plaintiffs' development of cancer. Dr. Melius' opinions were found to be scientifically acceptable, reliable and of assistance to the jury by United States District Judge Donetta W. Ambrose. *Hall v. Babcock & Wilcox Co.*, 69 F. Supp. 2d 716, 728 (W.D. Pa. 1999).

physician and also has an advanced degree as a Doctor of Public Health, which included graduate work in epidemiology and occupational and environmental health. Daubert Hearing, April 30, 2013, p. 117. Dr. Melius' public health and residency training included courses on the health effects and control of exposures to radiation and toxic materials in the workplace and environment as well as extensive work in epidemiology and biostatistics, including clinical evaluations of people with illnesses related to occupational or environmental exposures. Melius Report, p. 2. Currently, Dr. Melius serves as Chair of the federal Advisory Board on Radiation and Worker Health which provides oversight on the federal program to compensate former Department of Energy nuclear facility workers who have developed cancer and as Chair of the Steering Committee of the World Trade Center Responder Medical Programs which advises the federal government on the federal medical programs for rescue and recovery workers who were exposed at the World Trade Center subsequent to the terrorist attacks in 2001. *Id*. In his report, Dr. Melius opines that Plaintiffs' exposure to the ionizing radiation released from the Defendants' Apollo plant was a substantial contributing factor in each of the individual Plaintiffs' cancers.

Defendants argued, and Magistrate Judge Mitchell agreed, that Dr. Melius' opinions must be excluded under the standards of *TMI* because he makes no attempt to determine the dose Plaintiffs received from exposure to uranium, and because his causation opinions are not based upon any relevant epidemiologic evidence.

In *In re TMI*, the Third Circuit found that:

> The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research. Rather, the test is whether the "particular opinion is based on valid reasoning and reliable methodology." *Kannankeril v. Terminix International Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). . . The admissibility inquiry thus focuses on principles and methodology, not on the conclusions generated by

> the principles and methodology. *Id.* (citing *Paoli II* at 744). The goal is reliability, not certainty. Once admissibility has been determined, then it is for the trier of fact to determine the credibility of the expert witness. *Id.* (citing *Paoli II* at 743-746). "The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination." *Id.* Therefore, if the methodology and reasoning are sufficiently reliable to allow the fact finder to consider the expert's opinion, it is that trier of fact that must assess the expert's conclusions. The inquiry is a factual one, not a legal one.

In re TMI Litig., 193 F.3d at 665. Dr. Melius utilized differential diagnosis as his methodology in determining whether Plaintiffs' exposure to ionizing radiation was a substantial contributing factor in causing their cancers. The Third Circuit has "recognized 'differential diagnosis' as a technique that involves assessing causation with respect to a particular individual." *See Kannankeril v. Terminix Int'l*, 128 F.3d at 807.

The standard for differential diagnosis established in the Third Circuit provides that a physician need not rule out every possible cause "so long as he or she employed sufficient diagnostic techniques to have good grounds for his or her conclusion." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 761; *see also Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 156 (3d Cir. 1999) (an expert is "not required to rule out all alternative possible causes"). The elements of a differential diagnosis may consist of the performance of physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests. A doctor does not have to employ all of these techniques in order for the doctor's diagnosis to be reliable. *See In re Paoli*, 35 F.3d at 759. A differential diagnosis, therefore, may be reliable with less than all of the above mentioned types of information. *Id.*

This Court takes special note of the Third Circuit's treatment of the medical causation experts in the *Paoli PCB Litigation*. In *Paoli*, residents in the vicinity of a railcar maintenance facility at which polychlorinated biphenyls (PCBs) were used sought recovery for physical ailments and property damage from defendant corporations. The district court excluded virtually

all expert opinion and granted summary judgment for defendant corporations. The Third Circuit reversed the grant of summary judgment on certain claims that exposure to PCBs caused physical ailments finding that plaintiffs' medical expert testimony should not have been excluded.

Similar to the Defendants in the instant matter, the defense experts in *Paoli* leveled specific criticisms of the manner in which plaintiffs' doctors "engaged in differential diagnosis (to the point where they asserted that [such experts] had not even employed differential diagnosis)." *See In re Paoli*, 35 F.3d at 758. With this in mind, the court analyzed the application of the *Daubert* factors to the experts' differential diagnosis methodology, stating:

> Unfortunately, most of the *Daubert* factors -- testability, general acceptance, peer review, and degree of production of errors . . . are of only limited help in assessing whether the methodologies of [plaintiffs' doctors] are reliable (*i.e.* scientifically valid). We find that the final *Daubert* factor, the existence of standards controlling the technique's operation, is slightly more helpful in deciding whether the methodologies of the plaintiffs' doctors are reliable. . . .
>
> While applying the first *Daubert* factor, differential diagnosis can be considered to involve the testing of a falsifiable hypothesis (*e.g.* that PCBs caused a plaintiff's cancer) through an attempt to rule out alternative causes, that methodology involves far more elements of judgment than does a scientific study attempting to test a more general scientific proposition. While an important aspect of assessing scientific validity (and therefore evidentiary reliability) is the ability of other scientists to test or retest a proponent's theory, differential diagnosis involves assessing causation with respect to a particular individual. This merely makes it a different type of science than science designed to produce general theories; it does not make it unreliable science. Although in terms of the remaining *Daubert* factors, differential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results, it is a method that involves assessing causation with respect to a particular individual. As a result, the steps a doctor has to take to make that (differential) diagnosis reliable are likely to vary from case to case; the information a doctor needs in order to reliably assess the cause of a patient's lung cancer is often very different from the information needed to assess the cause of a patient's back or heart trouble. . . .
>
> Thus, although differential diagnosis is a generally accepted technique, no particular combination of techniques chosen by a doctor to assess an individual

> patient is likely to have been generally accepted. But unlike a methodology used in conducting a scientific study, lack of general acceptance is not a sign of unreliability, it is merely a result of the fact that the medical community will rarely have considered the reliability of a particular process of differential diagnosis used in an individual case. Nor is it likely that the particular combination will have been published and subject to peer review, because a particular version of differential diagnosis will rarely be of general interest to the medical community. However, to the extent that a doctor utilizes standard diagnostic techniques in gathering this information, the more likely we are to find that the doctor's methodology is reliable. For these reasons, we must be flexible in conducting our *Daubert* inquiry.

In re Paoli R.R. Yard PCB Litig., 35 F.3d at 758

In applying differential diagnosis in the area of occupational and environmental health, Dr. Melius described the methodology utilized in rendering his opinions as follows:

> [My approach] involved a number of steps and a number of factors. . . . I would review their residential and work history based on questionnaires they had filled out, based on depositions, and . . . information from their medical records. And that was supplemented by interviews with a number of the plaintiffs. . . I [also evaluated] where they lived, where they worked, how much time they would spend in proximity to the Apollo facility, where they went to school, whether their workplace was close to the facility, what other ways that they might have been exposed to . . . emissions from the Apollo facility in a way that I could . . . better understand that exposure. . . . The second part was to review their medical records to, one, confirm . . . that they were diagnosed with cancer and also to find out from going through their medical history what other factors, the personal risk factors, other factors such as smoking, that might have contributed to the development of their cancer. And so, I do a thorough review of the available medical records for those which were . . . very extensive.[5]

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[5] Similarly, in his deposition, Dr. Melius outlined his approach to differential diagnosis as follows:

> It is to review the person's medical record, their past medical history, the presence or absence of significant established risk factors for the illness, to what extent those people experienced or had those risk factors and those exposures, and to make an assessment as to whether or not those risk factors, including the environmental/occupational exposures, made a substantial contribution to the development of their -- that particular illness they have, cancer in this instance.

Melius Deposition p. 384.

Daubert Hearing, April 30, 2013, pp. 132-133. Dr. Melius also examined whether a Plaintiff had a history of exposure to another carcinogen, or a strong genetic factor which, by itself, could cause the occurrence of cancer. Daubert Hearing, April 30, 2013, pp. 135-136.

In addition, Dr. Melius testified that he also relied upon information with regard to the exposures to the Apollo emissions, which included the report of Dr. Ring, who evaluated the Apollo facility and the production and emission from the facility, the Franke report, both the supplement prepared in this litigation and the report prepared for the *Hall* litigation, the report of Dr. Ketterer regarding soil sampling in the Apollo area, and Dr. Hu's report. Daubert Hearing, April 30, 2013, pp. 139-140.

Dr. Melius explained why he did not rely upon, nor attempt to determine, a specific dose Plaintiffs received from exposure to the ionizing radiation, stating:

> . . . I don't believe that it's possible to do an accurate estimate of their exposure in a quantitative sense because I don't believe that there's adequate information available on the source, the amount of uranium handled at the facility, how that emitted through the stacks into the, into the community.
>
> There were a large number of stacks. There were limitations to the monitoring. And I don't believe that that can be adequately reconstructed from the soil sampling alone. So, I can't provide a quantitative estimate.
>
> There's also limitations to how one can evaluate quantitatively the exposures that people had. You don't know how much was emitted over time, what was in their area. People move around. . . . So, it's a very complicated exposure for the individual. So, I think all of those factors make it very difficult and I don't think it is possible to do an accurate exposure, re-creation, or estimate, for those individuals living in the Apollo area.

Daubert Hearing, April 30, 2013, pp. 141-142. Dr. Melius further explained that the majority of evaluations or "differential etiology" done in occupational environmental health are not based upon a full exposure quantification or assessment because such assessments are usually not available. *Id.* at p. 142. The approach utilized instead is a qualitative analysis based upon the

information available such as the source of exposure, how the source was emitted into the community and for what period of time, to determine whether the exposure contributed to a particular illness. *Id.* at pp. 142-144. Dr. Melius testified that a qualitative assessment of carcinogenic exposure is commonly utilized in the field of occupational environmental health. *Id.* at p. 145.

Dr. Melius explained that his approach in the instant matter was not much different than his approach in the *Hall* case. Though Franke's Report in this matter did not include dose specific calculations for the Plaintiffs, Dr. Melius had access to Franke's Report from the *Hall* case and testified to its limitations. Specifically, in explaining why he opined the exposures were well in excess of the background rate, Dr. Melius stated:

> There was a number of documented accidental releases where large amounts of material were released into the air. Mr. [Franke] provided some exposure estimates from one of those. There were a number of others that were reported, some that may have occurred that weren't reported. And I believe that for a number of them there were not very adequate records to document the timings or the amounts on many of those. But I think it's clear that they, many of those did occur. . . . [These exposures] would be above background. . . . [T]he acute releases and the general releases would be, could lead to exposures that were greater than background, numerically. Again, because of the record on emissions is so incomplete, it's hard to quantitate them very specifically. One can make some assessments. Certainly, in the earlier *Hall* case there was an evaluation made. I'm trying to look at the exposures and those estimates for the individual plaintiffs in that trial. There were significant limitations to that as discussed at that trial [admitted] by the people that did those evaluations because, largely, they were based mainly on the soil data. So, I think we've referred to them in that case as being sort of low limits or, certainly, recognized that they significantly under-estimated what people's exposures would have been.

Id. at p. 148-149. When pressed by Defendants contending that reference to dose was a "fundamental pillar[]" of his opinions regarding causation of the plaintiffs' cancers in the *Hall* case, and his failure to estimate a minimum dose in the instant matter, Dr. Melius reiterated:

> We did not quantitate a minimal dose. I included the original [Franke] report as a

> reference. So, that was, in essence, incorporated and I included the Thorne[6] estimates. So, that was part of the, you know, the exposure information I had. And I believe that, I believe that it's a mischaracterization to call the Thorne estimates a pillar of that original case. There were a number of shortcomings to those, those estimates and that exposure assessment. They, basically, used it more as some indication of exposure, some indication that particularly organs could be, receive dose. But it was a very severe under-estimate of exposure, given the limitations of the facts available to the people doing the initial, the exposure reconstruction and then that, in turn, being fed into the dose estimates that Dr. Thorne did. So, they were not used directly to make the assessment of the individual plaintiffs, as I recall.

Id. at p. 156-157.

The court in *TMI* did not require a plaintiff prove a quantified dose in order to prove personal injuries caused by the release of radiation. As set forth above, plaintiffs must establish; the release of radiation in excess of the levels permitted by federal regulations; exposure-although not necessarily at levels prohibited by those regulations; and injury caused by the exposure to radiation. *See In re TMI Litig.*, 193 F.3d at 659. The Third Circuit has previously recognized that hard evidence of the level of exposure is unnecessary for a medical expert to opine that exposure to a chemical caused a plaintiff's illness. In both *Heller v. Shaw Industries, Inc.* and *Kannankeril v. Terminix Int'l*, the Third Circuit, in the context of civil actions where the plaintiffs were proffering expert medical testimony based upon differential diagnosis, found that the types of evidence used in supporting a theory of exposure of a plaintiff to a chemical is a question of credibility, not admissibility. The Court in *Kannankeril* stated:

> Under the facts as presented in this case, the district judge erred in ruling that an expert may rely only on the ambient air test to determine whether Dr. Kannankeril had been exposed to Dursban. Instead, all factual evidence of the presence of the chemicals in the residence should be relevant in forming an expert opinion of causation.
>
> We conclude that it is for the trier of fact to determine what weight to give the ambient air test results as an indication of exposure. *See Joiner v. General Elec.*

[6] Dr. Thorne is a dosimetry expert who provided dose estimates in the *Hall* case.

> *Co.*, 78 F.3d 524, 534 (11th Cir.1996) (reversing exclusion of expert opinions that plaintiffs' exposure to certain chemicals caused his lung cancer where there were issues of fact whether plaintiff was actually exposed to the chemicals so that summary judgment based on a finding of no exposure was inappropriate). The issue whether an ambient air test should be given more weight than pesticide application records goes to the weight rather than the admissibility of evidence. *See United States v. Velasquez*, 64 F.3d 844, 848, 33 V.I. 265 (3d Cir.1995) (citing *United States v. Jakobetz*, 955 F.2d 786, 800 (2d Cir.1992)). The trial judge must be careful not to mistake credibility questions for admissibility questions.

Kannankeril v. Terminix Int'l, 128 F.3d at 808-809.

Both the Fourth Circuit and the Eighth Circuit made similar findings with regard to requiring expert evidence of specific dose. In *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999), the court held that, in general, "a reliable differential diagnosis provides a valid foundation for an expert opinion," *id.* at 263, and that the expert's diagnosis was admissible because it was "clearly [] not a case in which the plaintiff was unable to establish any substantial exposure to the allegedly defective product. . . [A]lthough [the physician] did not point to [the plaintiff's] exposure to a specific level . . ., there was evidence of a substantial exposure." *Id.* at 265. Likewise, in *Bonner v. ISP Techs., Inc.*, 259 F.3d 924 (8th Cir. 2001), the Eighth Circuit held that "it was not necessary that [the plaintiff's] experts quantify the amount of [the product] to which she was exposed in order to demonstrate that she was exposed to a toxic level of [the chemical]" as "[i]t is sufficient for a plaintiff to prove that she was exposed to a quantity of toxin that 'exceeded safe levels.'" *Id.* at 931.

Recognizing that Dr. Melius is opining based upon a qualitative analysis and not a quantitative dose analysis, the Court finds enough support in the record for the contention that the Plaintiffs' exposure levels exceeded the normal background level. Plaintiffs were present during the periods of release, both acute and general, and were exposed to ionized radiation, a carcinogen known to cause the injuries complained of in this matter. Moreover, the record is

replete with NUMEC's failure to monitor emissions and its failure to retain accurate records regarding inventory, yields and process losses related to uranium. A quantitative dose calculation, therefore, may in fact be far more speculative than a qualitative analysis. The Court agrees with Plaintiffsthat a jury could well infer that persons living, working, or otherwise spending time, in the affected area were regularly and frequently exposed to a substantial, though unquantifiable, dose[7] of iodized radiation emitted from the Apollo facility.

The Court also finds that Dr. Melius adequately addressed other possible causes of Plaintiffs' cancers, both known and unknown. Dr. Melius reviewed Plaintiffs' residential and work history based on questionnaires they had filled out, reviewed depositions, did an extensive review of the medical records and histories, and interviewed a number of the plaintiffs. Dr. Melius took into account any risk factor that would, on its own, account for Plaintiffs' cancers. Dr. Melius also had information on the history of radiation in the Apollo area, and the level of radiation in soil samples in the area. Based on his review, Dr. Melius made a determination whether the exposure to iodizing radiation was a substantial contributing factor to a Plaintiff's injury.

The standard established in the Third Circuit provides that a physician need not rule out every possible cause as long as he or she employed sufficient diagnostic techniques to have good

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[7] Moreover, several courts have concluded that precise levels of exposure are not necessary regarding radiation as there is no safe level of radiation exposure. *See In re TMI*, 193 F.3d at 642 (". . . there is no threshold dose below which the probability of cancer is zero."); *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1137 (9th Cir. 2002) ('Radiation is capable of causing a broad range of illnesses, even at the lowest doses."); *In re Three Mile Island Litigation*, 193 F.3d 613, 643 (3d Cir. 1999) ("there is scientific consensus that ionizing radiation can cause cancer").

grounds for his or her conclusion.[8] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 761. In *Heller*, the Court of Appeals held that it is an error of law to exclude expert testimony on the basis that an expert failed to rule out all alternative possible causes when conducting a differential diagnosis. *Heller v. Shaw Industries, Inc*., 167 F.3d at 156. A plaintiff "need not exclude every possible explanation of the [injury]; it is enough that reasonable minds are able to conclude that the preponderance of the evidence shows defendant's conduct to have been a substantial cause of the harm to plaintiff." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at761 (quoting *Hamil v. Bashline*, 392 A.2d 1280, 1284 (Pa. 1978)). Moreover, an attempt to rule out alternative causes in cancer cases, applying a differential diagnosis methodology, "involves far more elements of judgment than does a scientific study attempting to test a more general scientific proposition." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 758.

Defendants also contend that Dr. Melius' opinions must be excluded because his causation opinions are not based upon any relevant epidemiologic evidence. Dr. Melius testified that he reviewed, but did not rely upon, the Apollo-Parks Cancer Incidence Study from 1984-1992, published in 1996 by the Pennsylvania Department of Health, which shows a statistically significant increase in the incidence of cancer in the Apollo area as compared with surrounding areas. Dr. Melius Deposition 1/8/2013 pp. 15-17; Daubert Hearing, April 30, 2013, pp. 158-160. These studies found a statistically significant 15% increased incidence of cancer in the

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[8] As Professor Capra, Reporter to the Advisory Committee on the Federal Rules of Evidence, stated:

> To require the experts to rule out categorically all other possible causes for an injury would mean that few experts would ever be able to testify . . . .
> . . . Obvious alternative causes need to be ruled out. All possible causes, however, cannot be and need not be eliminated before an expert's testimony will be admitted.

Daniel J. Capra, *The Daubert Puzzle*, 32 GA. L. REV. 699, 728 (1998).

municipalities closest to the plant. Dr. Melius, however, testified that in forming his opinions he reviewed Dr. Hu's Report which relied upon the body of epidemiology studies of populations exposed to ionizing radiation.

The Court finds Dr. Melius' use of epidemiology studies of populations exposed to ionizing radiation to be adequate in concert with his differential diagnosis as a method of assessing causation. Moreover, many courts have held that epidemiological evidence is not the sole method of establishing causation. *See Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002) (Epidemiology, a field that concerns itself with finding the causal nexus between external factors and disease, is generally considered to be the best evidence of causation in toxic tort actions. . . [however] the lack [of epidemiological studies] is not fatal to a plaintiff's case."); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 992 (8th Cir. 2001) (noting "the absence of epidemiological evidence did not doom [plaintiff's] case"); *In re Joint E. & S. Asbestos Litig.*, 964 F.2d 92, 97 (2d Cir. 1992) (plaintiff relied on clinical evidence as well as epidemiological studies to prove causation); *Caraker v. Sandoz Pharms. Corp*., 188 F. Supp. 2d 1026, 1033 (S.D. Ill. 2001) ("this Court imposes no absolute epidemiology requirement").

Dr. Melius' opinion regarding Plaintiffs' exposures to ionizing radiation and the resulting cancers is not novel scientific theory. Dr. Melius has demonstrated good grounds for his opinions that the exposure to the radiation emitted from the Apollo plant was a substantial contributing factor in the development of Plaintiffs' cancers. Accordingly, the motions to exclude his testimony will be denied.

3. Bernd Franke and Joseph Ring, Ph.D.

Bernd Franke, ("Franke"), the Scientific Director at the Institute for Energy and Environmental Research in Heidelberg, Germany, was retained by the Plaintiffs to provide an

expert opinion regarding the amount of ionizing radiation in the form of enriched uranium that was released from the Apollo facility and how such emissions exceeded federal permissible regulations during the operational life of the Apollo facility. Franke co-authored a 1998 report titled "Radiation Exposures in the Vicinity of Uranium Facility in Apollo, Pennsylvania" (the "1998 Report"), which he updated in an affidavit dated April 23, 2012 (the "2012 Affidavit").

Franke's 2012 Affidavit recreated a hypothetical dose estimate for an individual exposed to ionizing radiation released from a 1963 incident, specifically a vault fire, at the Apollo facility. Plaintiffs contend that the recreation of the incident was done to determine the nature and extent of radiation exposure to an individual present during such incident and to aid in understanding the magnitude of the radiation exposures members of the public would have received from the many other known accidents at the Apollo facility.

Franke's testimony was given to support the contention that emissions from the Apollo plant routinely exceeded federal permissible limits for airborne emissions, an element Plaintiffs must establish to prove personal injury caused by the release of radiation. Specifically, Franke concluded that the radioactive emissions from the Apollo plant violated 10 C.F.R. § 20.106 each and every year of production between the years of 1963 through 1979. *See* 1998 Report, Table 4, p. 28. Further, Franke's calculations from the 1963 vault fire incident demonstrate that the short-term releases of highly enriched uranium would have resulted in significant exposures to members of the public in the vicinity of the plant during the accident. Plaintiffs assert that both Franke's findings set forth in Table 4 and his proposed testimony with regard to the vault fire are evidence that Defendants breached their duty of care by regularly violating the Federal Regulations set forth at 10 C.F.R. § 20.105 and 10 C.F.R. § 20.106.

Defendants do not contest Franke's methodology or his qualifications. Defendants argue

that Franke's opinion does not "fit" the relevant inquiries regarding breach of duty and causation in the instant cases. Specifically, Defendants argue that Franke failed to perform a dose specific calculation for each Plaintiff, he failed to read Plaintiffs' depositions and questionnaires, and relied upon a hypothetical "scenario calculation" with no basis in fact.

Magistrate Judge Mitchell concluded that because Franke failed to calculate the dose of radiation received by any Plaintiff in these cases, his "testimony does not 'fit' the breach of duty element . . . because without a calculation of dose, it would not aid the trier of fact in resolving the issue of causation." R & R at p. 24. This Court agrees that Frank's opinion does not aid the finder of fact with regard to causation, however, Franke's opinion does "fit," and is relevant to, the first two elements of a negligence cause of action: (1) a legal duty requiring a defendant to conform to a certain standard of conduct and (2) a failure to conform to that standard.

The Court of Appeals for the Third Circuit held that the federal standard of care in public liability actions was governed by 10 C.F.R. §§ 20.105 and 20.106 and that "the duty of care is measured by whether Defendants released radiation in excess of the levels permitted by §§ 20.105 or 20.106, as measured at the boundary of the facility, not whether each plaintiff was exposed to those excessive radiation levels." *In re TMI*, 67 F.3d at 1117-1118. *See also Hall v. Babcock & Wilcox Co.*, 69 F. Supp. 2d 716, 730 (W.D. Pa. 1999). The Court further stated that after a violation of a statute or regulation has been determined, the first two elements of a negligence cause of action are satisfied. *In re TMI* at 1118. Before they may recover, however, Plaintiffs "must still prove causation and damages . . ." *Id.*

As set forth above, Franke updated the calculations in his 1998 Report regarding a hypothetical dose estimate for an individual exposed to ionizing radiation released from a 1963 incident. Specifically, Franke stated:

> The revised results clearly indicate that as short-term release of 3 kg of highly enriched uranium would have resulted in significant exposures and subsequent radiation doses to members of the public who were present in the vicinity of the plant during the accident. Up and including 1979, the lung dose limits for residents was 1.5 rem; the accidental exposure could thus have resulted in doses that were up to 280 times larger than the permissible lung dose for 1963.

2012 Affidavit ¶ 7. Franke's findings demonstrate that Defendants "regularly and repeatedly" violated the standard of care identified in 10 C.F.R. §§ 20.105 and 20.106. Franke's opinion, therefore, is directly applicable to proving that Defendants breached their duties to Plaintiffs and to the public. Moreover, Franke identifies the specific radionuclide, highly enriched uranium, and the plant from which it originated. Additionally, Franke's review of aerial emissions data provided by NUMEC, and his soil analysis, as well as the work of Dr. Michael Ketterer[9], demonstrate the geographic extent of the contamination from the plume of ionizing radiation to which Plaintiffs would have been exposed. Accordingly, Franke's opinion is relevant to Defendants' alleged breach of the standard of care, and Defendants' motion to exclude such opinion will be denied.

Similarly, Defendants argue that Dr. Ring's opinion must be excluded on the grounds he did not perform a "dose-specific" calculation for each Plaintiff. Dr. Ring is a radiation safety officer with a doctorate in physics/radiological sciences, retained by Plaintiffs to render an expert opinion regarding the radiation protection practices used at Defendants' Apollo facility. Based upon his review of the data, records and transcripts provided by the parties, as well as his own research, Dr. Ring summarized his opinion about NUMEC's operations as follows:

> [B]oth the Apollo and the Parks facilities failed to meet the minimum standards of safety for a nuclear facility. In violation of federal law, each of these facilities regularly emitted large amounts of radioactive material into the surrounding

[9] Michael Ketterer, Ph.D. is a chemist who analyzed soil samples from around the Apollo facility in March of 2012, and was retained by Plaintiffs to provide an expert report, analysis and opinion about sources of uranium near the Apollo facility.

> environment through airborne stack emissions, unfiltered stack emissions, ventilation problems, unsecured material handling, fugitive dust, and failed to properly monitor and report its radioactive emissions to the appropriate regulatory agencies. Moreover, these releases regularly and consistently exceeded federal regulatory limits.

Ring Report, p. 4.

The Court finds no need to emphasize the specifics of Dr. Ring's findings, as neither his methodology nor qualifications are questioned, and his opinion clearly fits and is relevant to Defendants' duty to Plaintiffs and the surrounding public, and their consistent breach of such duty. A "dose-specific" calculation, therefore, is irrelevant to the elements of Plaintiffs' case to which Dr. Ring's opinion is directed. Defendants' motion to exclude Dr. Ring's opinion shall also be denied.

B. Defendants' Experts

Though Plaintiffs' disagree, the Court finds that review of the Magistrate Judge's rulings on Plaintiffs' motions to exclude the expert opinions and testimony Defendants' experts falls within the purview of 28 U.S.C. § 636(b)(1)(A) and Rule 72 (a) of the Federal Rules of Civil Procedure. This Court, therefore, reviews such rulings under a "clearly erroneous or contrary to law" standard.[10] *See* 28 U.S.C. § 636(b)(1)(A); FED. R. CIV. P 72 (a); *see also Haines v. Liggett Group, Inc.*, 975 F.2d 81, 91-92 (3d Cir. 1992).

A finding is contrary to law if the magistrate judge has misinterpreted or misapplied applicable law. "A finding is 'clearly erroneous' when, although there is evidence to support it, the reviewing court on consideration of the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Lo Bosco v. Kure Engineering Ltd.*, 891 F. Supp. 1035, 1037 (D.N.J. 1995) (quoting *United States v. Gypsum Co.*, 333 U.S. 364, 395 (1948)).

[10] Based on the above analysis of the viability of Plaintiffs' expert opinions, the Court doubts that a *de novo* review of Defendants' experts would yield a different result.

Based on a comprehensive review of the record, the Court finds that Magistrate Judge Mitchell's rulings on Plaintiffs' motions to exclude Defendants expert opinions and testimony are neither clearly erroneous nor contrary to law. Accordingly, the motions to exclude will be denied.

III. CONCLUSION

Based on the foregoing: (1) Defendants' Motions to Exclude Expert Opinions of Mr. Bernd Franke and Joseph Ring, Ph.D., will be denied; (2) Defendants' Motions to Exclude Expert Testimony and Opinions of Donal Kirwan will be denied; (3) Defendants' Motions to Exclude Expert Opinions of Dr. Howard Hu will be denied; (4) Defendants' Motions to Exclude Testimony of James Melius will be denied; (5) Plaintiffs' Motions to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Expert John E. Till Ph.D. will be denied; (6) Plaintiffs' Motions to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Experts Dr. Christopher Whipple and Stanley Hayes will be denied; (7) Plaintiffs' Motions to Exclude Testimony and Report of Fred A. Mettler, Jr., M.D., M.P.H. will be denied; and (8) Plaintiffs' Motions to Exclude Testimony and Studies of Dr. John D. Boice, Jr. will be denied. An appropriate Order follows.

Cercone, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MICHELLE MCMUNN, Personal Representative of the Estate of EVA MYERS, et al., Plaintiffs,	)	
v.	)	2:10cv143
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

JESSI ANN CASELLA, et al., Plaintiffs,	)	
v.	)	2:10cv368
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

MICHAEL P. HUTH, et al., Plaintiffs,	)	
v.	)	2:10cv650
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

LINDA W. DILIK, Plaintiff,	)	
v.	)	2:10cv728
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

BONNIE AIKENS, et al.,	)	
Plaintiffs,	)	
v.	)	2:10cv744
	)	Electronic Filing
BABCOCK & WILCOX POWER	)	
GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

PATRICIA ALTIMIRE, et al.,	)	
Plaintiffs,	)	
v.	)	2:10cv908
	)	Electronic Filing
BABCOCK & WILCOX POWER	)	
GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

MARCIA BAUSTERT, et al.,	)	
Plaintiffs,	)	
v.	)	2:11cv898
	)	Electronic Filing
BABCOCK & WILCOX POWER	)	
GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

SANDRA L. AMENT, et al.,	)	
Plaintiffs,	)	
v.	)	2:11cv1381
	)	Electronic Filing
BABCOCK & WILCOX POWER	)	
GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

ELIZABETH MITCHESON, et al.,	)	
Plaintiffs,	)	
v.	)	2:12cv1221
	)	Electronic Filing
BABCOCK & WILCOX POWER	)	
GENERATION GROUP, INC., et al.,	)	
Defendants.	)	

KAREN L. SKROUPA, as personal representative of HOWARD D. SKROUPA, deceased, Plaintiff,	)	
v.	)	2:12cv1459
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

HEATHER LORRAINE BAYNAR, et al., Plaintiffs,	)	
v.	)	2:10cv1736
	)	Electronic Filing
BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants.	)	

ORDER OF COURT

AND NOW, this 27th day of February, 2014, upon consideration of the several Motions to Exclude Expert Opinions and Testimony filed on behalf the parties, the responses, the briefs and appendices filed in support thereof, and the hearings held on April 30, 2013 and May 1, 2013, in accordance with the Memorandum Opinion filed herewith,

IT IS HEREBY ORDERED as follows: (1) Defendants' Motions to Exclude Expert Opinions of Mr. Bernd Franke and Joseph Ring, Ph.D., (**Document No. 201** at 2:10cv143; **Document No. 160** at 2:10cv368; **Document No. 152** at 2:10cv650; **Document No. 169** at 2:10cv728; **Document No. 169** at 2:10cv744; **Document No. 185** at 2:10cv908; **Document No. 157** at 2:10cv1736; **Document No. 101** at 2:11cv898; **Document No. 81** at 2:11cv1381; **Document No. 26** at 2:12cv1221; and **Document No. 25** at 2:12cv1459) are **DENIED**; (2) Defendants' Motions to Exclude Expert Testimony and Opinions of Donal Kirwan (**Document No. 205** at 2:10cv143; **Document No. 164** at 2:10cv368; **Document No. 156** at 2:10cv650; **Document No. 173** at 2:10cv728; **Document No. 173** at 2:10cv744; **Document No. 189** at

2:10cv908; **Document No. 161** at 2:10cv1736; **Document No. 105** at 2:11cv898; **Document No. 85** at 2:11cv1381; **Document No. 30** at 2:12cv1221; and **Document No. 29** at 2:12cv1459) are **DENIED**; (3) Defendants' Motions to Exclude Expert Opinions of Dr. Howard Hu (**Document No. 209** at 2:10cv143; **Document No. 176** at 2:10cv368; **Document No. 170** at 2:10cv650; **Document No. 187** at 2:10cv728; **Document No. 183** at 2:10cv744; **Document No. 199** at 2:10cv908; **Document No. 173** at 2:10cv1736; **Document No. 117** at 2:11cv898; **Document No. 95** at 2:11cv1381; **Document No. 46** at 2:12cv1221; and **Document No. 45** at 2:12cv1459) are **DENIED**; (4) Defendants' Motions to Exclude Testimony of James Melius (**Document No. 214** at 2:10cv143; **Document No. 168** at 2:10cv368; **Document No. 160** at 2:10cv650; **Document No. 177** at 2:10cv728; **Document No. 177** at 2:10cv744; **Document No. 193** at 2:10cv908; **Document No. 165** at 2:10cv1736; **Document No. 109** at 2:11cv898; **Document No. 89** at 2:11cv1381; **Document No. 34** at 2:12cv1221; and **Document No. 33** at 2:12cv1459) are **DENIED**; (5) Plaintiffs' Motions to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Expert John E. Till Ph.D. (**Document No. 221** at 2:10cv143; **Document No. 174** at 2:10cv368; **Document No. 166** at 2:10cv650; **Document No. 183** at 2:10cv728; **Document No. 189** at 2:10cv744; **Document No. 205** at 2:10cv908; **Document No. 171** at 2:10cv1736; **Document No. 115** at 2:11cv898; **Document No. 100** at 2:11cv1381; **Document No. 40** at 2:12cv1221; and **Document No. 39** at 2:12cv1459) are **DENIED**; (6) Plaintiffs' Motions to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Experts Dr. Christopher Whipple and Stanley Hayes (**Document No. 223** at 2:10cv143; **Document No. 182** at 2:10cv368; **Document No. 168** at 2:10cv650; **Document No. 185** at 2:10cv728; **Document No. 191** at 2:10cv744; **Document No. 207** at 2:10cv908; **Document No. 178** at 2:10cv1736; **Document No. 123** at 2:11cv898; **Document No. 103** at 2:11cv1381; **Document**

No. 42 at 2:12cv1221; and **Document No. 41** at 2:12cv1459) are **DENIED**; (7) Plaintiffs' Motions to Exclude Testimony and Report of Fred A. Mettler, Jr., M.D., M.P.H. (**Document No. 225** at 2:10cv143; **Document No. 184** at 2:10cv368; **Document No. 172** at 2:10cv650; **Document No. 193** at 2:10cv728; **Document No. 193** at 2:10cv744; **Document No. 209** at 2:10cv908; **Document No. 181** at 2:10cv1736; **Document No. 125** at 2:11cv898; **Document No. 105** at 2:11cv1381; **Document No. 44** at 2:12cv1221; and **Document No. 43** at 2:12cv1459) are **DENIED**; and (8) Plaintiffs' Motions to Exclude Testimony and Studies of Dr. John D. Boice, Jr. (**Document No. 227** at 2:10cv143; **Document No. 186** at 2:10cv368; **Document No. 178** at 2:10cv650; **Document No. 195** at 2:10cv728; **Document No. 195** at 2:10cv744; **Document No. 211** at 2:10cv908; **Document No. 183** at 2:10cv1736; **Document No. 127** at 2:11cv898; **Document No. 107** at 2:11cv1381; **Document No. 52** at 2:12cv1221; and **Document No. 46** at 2:12cv1459) are **DENIED**.

IT IS FURTHER ORDERED that the Report and Recommendation of the Magistrate Judge (**Document No. 271** at 2:10cv143; **Document No. 229** at 2:10cv368; **Document No. 220** at 2:10cv650; **Document No. 238** at 2:10cv728; **Document No. 240** at 2:10cv744; **Document No. 257** at 2:10cv908; **Document No. 224** at 2:10cv1736; **Document No. 169** at 2:11cv898; **Document No. 153** at 2:11cv1381; **Document No. 98** at 2:12cv1221; and **Document No. 96** at 2:12cv1459) is ADOPTED with regard to Defendants' Motions to Exclude Expert Testimony and Opinions of Donal Kirwan, Plaintiffs' Motions to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Expert John E. Till Ph.D., Plaintiffs' Motions to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Experts Dr. Christopher Whipple and Stanley Hayes, Plaintiffs' Motions to Exclude Testimony and Report of Fred A. Mettler, Jr., M.D., M.P.H., and Plaintiffs' Motions to Exclude Testimony and Studies of Dr. John D. Boice,

Jr. Plaintiffs' objections to the Report and Recommendation regarding Defendants' Motions to Exclude Expert Opinions of Mr. Bernd Franke and Joseph Ring, Ph.D., Defendants' Motions to Exclude Expert Opinions of Dr. Howard Hu, and Defendants' Motions to Exclude Testimony of James Melius are **GRANTED**.

s/ David Stewart Cercone
David Stewart Cercone
United States District Judge

cc: Robert C. Mitchell
United States Magistrate Judge

Jason T. Shipp, Esquire
David B. Rodes, Esquire
Anne Kearse, Esquire
Bruce E. Mattock, Esquire
Victoria Antion, Esquire
Fidelma Fitzpatrick, Esquire
Jonathan D. Orent, Esquire
Michaela S. McInnis, Esquire
Chris Michael Temple, Esquire
Christopher M. Mooney, Esquire
John P. Phillips, Esquire
Peter C. Meier, Esquire
Matthew H. Meade, Esquire
Nancy G. Milburn, Esquire
Philip H. Curtis, Esquire
Reuben S. Koolyk, Esquire
Caley M. Heekin, Esquire
Elisa M. Pandolfi, Esquire
Jarrod Shaw, Esquire
Edward A. Bayley, Esquire
Joel D. Rohlf, Esquire
Jonathan I. Coronel, Esquire
Sean M. Callagy, Esquire
Simona A. Agnolucci, Esquire
Kevin M. Henley, Esquire
Mary E. Sylvester, Esquire
Matthew D. Grant
Tanya E. Kalivas, Esquire

(*Via CM/ECF Electronic Mail*)