UNIVERSITY NANO LABS: ASSESSING AND MINIMIZING ENVIRONMENTAL, HEALTH, AND SAFETY RISKS

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INTRODUCTION

Nanotechnology is the science of the very small. As materials are reduced in size such that they reach nanometer[1] proportions, some begin to act and react in ways very different from their larger scale counterparts. Nanoscale silver has antimicrobial properties.[2] Gold changes color to red.[3]

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1. One nanometer equals one billionth of a meter.

2. Georgios A. Sotirou & Sotiris E. Pratsinis, *Antibacterial Activity of Nanosilver Ions and Particles*, 44 ENVTL. SCI. & TECH. 5649 (2010); Atousa Moazami et al., *Antibacterial Properties of Raw and Degummed Silk with Nanosilver in Various Conditions*, 111 J. APPLIED POLYMER SCI. 253 (2010).

3. Meggie Lu, *Nanogold Bio-Sensor May Allow People to Detect Cancer*

Alumina is highly explosive. Carbon can conduct heat and electricity as well as metals.[4] Most materials need to be reduced to 100 nanometers ("nm") or less for these unique properties to become evident.[5] To put this in perspective, the head of a pin is 1,000,000 nm across, a human hair is 50,000–100,000 nm in diameter, and a human red blood cell is about 6,000 nm.[6]

Looking for the next driver of economic growth, the federal government, along with many governments around the world, is investing heavily in the development of nanoscale technology.[7] Many of those dollars are being directed to colleges and universities,[8] which conduct most of the basic nanoscale research and make many of the discoveries about the way materials act at the nanoscale.[9] Along with basic research, applied research

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Through At-Home Test, TAIPEI TIMES, Feb. 17, 2009, at 2, *available at* http://www.taipeitimes.com/News/taiwan/archives/2009/02/17/2003436326.

4. Norihiro Kobayashi et al., *Risk Assessment of Manufactured Nanomaterials – Carbon Nanotubes (CNTs)*, Executive Summary, October 16, 2009, New Energy and Industrial Technology Development Organization (NEDO), Tokyo, Japan, http://goodnanoguide.org/tiki-download_wiki_attachment.php?attId=31. When formed into structures known as carbon nanotubes ("CNT") with diameters of 100 nm or less, CNT's have metal and semiconducting characteristics. They are being used in many electronic applications, such as wiring materials, lithium ion batteries, conductive resins and others. Richard Van Noorden, *The Trials of New Carbon*, 469 NATURE 14 (2011), *available at* http://www.nature.com/news/2011/110105/full/469014a.html.

5 John F. Sargent Jr., CRS Report RL34511, *Nanotechnology: A Policy Primer* (2010), *available at* http://www.fas.org/sgp/crs/misc/RL34511.pdf. While 999 nm is technically nano scale, most materials do not reveal unique physio-chemical properties until at least one dimension of the particle is 100 nm or less.

6. Andrew Maynard, *The Twinkie Guide to Nanotechnology*, Oct. 22, 2007, http://www.nanotechproject.org/news/archive/the_twinkie_guide_to_nanotechnology/ (last visited Jan. 24, 2011).

7. Lux Research, *U.S. Risks Losing Global Leadership in Nanotech, Says Lux Research*, TEKRATI.COM (Aug 18, 2010), http://semiconductors.tekrati.com/research/11202/#.

8. *See, e.g.*, Office of Science and Technology Policy, *NNI Strategic Plan 2010*; Request for Information, 75 Fed. Reg. 38,850 (July 6, 2010); Britt E. Erickson, *Nanotechnology Investment: U.S. Focuses on Commercialization and Strengthening Environmental, Health, and Safety Research*, CHEM. & ENG. NEWS, Apr. 12, 2010, *available at* http://pubs.acs.org/cen/government/88/8815gov1.html; Phil Harvey, *Why Small is the New Big*, D. MAG., Jan. – Feb. 2011, http://www.dmagazine.com/Home/D_CEO/2011/January_February/Technology_Issue/North_Texas_Research_Pushes_Future_of_Nanotechnology.aspx?p=1; Bruce P. Mehlman, Assistant Secretary for Technology Policy, U.S. Dept. Com., *Technology Administration - The Federal Government's Role in Nanotechnology Research, Development & Commercialization*, http://www.nist.gov/tpo/publications/speechtransfedgovroleinnano.cfm (last visited Jan. 24, 2011).

9. Chris Barncard, *Federal Investment in Basic Research Yields Outsized Dividends*, NANOTECH. NOW, May 14, 2010, *available at* http://www.nanotech-now.com/news.cgi?story_id=38220 (last visited Jan. 24, 2011); Yin Xia, *Productivity of Nanobiotechnology Research and Education in U.S. Universities*, Presentation to the 2009 Annual Meeting of the Agricultural and Applied Economics Association, July 26-

is increasingly important as colleges and universities more often become active participants in commercial development projects.[10]

Products containing nanoscale materials are used in a diverse collection of industries.[11] Stepping backward in the product development chain, this industrial diversity means that nanoscale research is being conducted in a wide variety of labs within a university or college, be it food science, material science, chemistry, textile science, aerospace, biomedics, electronics, or engineering, among others.

The very properties that entice researchers and scientists to nanoscale materials also give cause for concern. Regulators, legislators, and activists are increasingly questioning whether nanomaterials may present a risk to human and environmental health.[12] In Europe especially, many interest groups are calling for a complete ban on the use of nanomaterials, especially in foods and consumer products.[13] If small enough, some nanomaterials can penetrate the cell wall.[14] This is beneficial if the

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28, 2009, Milwaukee, WI, http://econpapers.repec.org/paper/agsaaea09/49442.htm.

10. *See, e.g.*, Jue Wang & Philip Shapira, *Partnering with Universities: A Good Choice for Nanotechnology Start-up Firms?*, SMALL BUS. ECON., Dec. 10, 2009; Gwyneth K. Shaw, *In Albany, A Public-Private Hybrid Aims To Bring Nano To The Marketplace*, NEW HAVEN INDEP., Jan. 11, 2011, *available at* http://www.newhavenindependent.org/index.php/archives/entry/ualbanys_public-private_hybrid_a_model_for_bringing_nano_to_the_marketplace/.

11. Nanoscale materials are making their way into the consumer marketplace at an increasing pace. The Woodrow Wilson Institute's Project on Emerging Nanotechnologies has listed over 1000 consumer products that contain nanomaterials. *See* Nanotechnology Project, http://www.nanotechproject.org/inventories/consumer/ (last visited Jan. 24, 2011). The number of consumer products that contain nanomaterials has grown at a sixty percent annual rate over the last five years. *See* Nanotechnology Project, http://www.nanotechproject.org/inventories/consumer/analysis_draft/ (last visited Jan. 24, 2011). A broad array of products are utilizing nanoscale materials to help make them lighter, stronger, corrosion resistant, more durable, more reactive, more bio-available, and more economical. These include sporting goods, athletic wear, textiles, automobile components, food packaging, cosmetics, personal care products, medicines and medical devices, electronics, solar cells, lubricants, building materials, basic materials, chemicals, paints and coatings and many others. *See* Nanotechnology Project, http://www.nanotechproject.org/inventories/consumer/browse/categories.

12. *See, e.g.*, Nanotechnology Safety Act of 2010, S. 2942, 111th Cong. (2010); Nat'l Inst. for Occup'l Safety & Health, *Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers* (2010), *available at* http://www.cdc.gov/niosh/docket/review/docket161A/pdfs/carbonNanotubeCIB_PublicReviewOfDraft.pdf; Friends of the Earth, *Nanosunscreens Threaten Your Health*, http://www.foe.org/healthy-people/nanosunscreens (last visited Jan. 24, 2011).

13. *See, e.g.*, Food & Water Watch, *Unseen Hazards: from Nanotechnology to Nanotoxicity*, at 11, http://documents.foodandwaterwatch.org/nanotech-unseen-hazards.pdf (last visited Jan. 24, 2011).

14. *See, e.g.*, Dmitry I. Kopelevich et al., *Potential Toxicity of Fullerenes and Molecular Modeling of their Transport across Lipid Membranes*, *in* NANOSCIENCE AND NANOTECHNOLOGY: ENVIRONMENTAL AND HEALTH IMPACTS, 235, 237 (V.H. Grassian ed., 2008).

material is delivering a pharmaceutical and potentially hazardous otherwise. It is not that nanomaterials are inherently dangerous; it is that the dangers are unknown.

The nature of this kind of research is iterative trial and error. First, lab personnel discover how to create a nanoscale version of a chemical or material; second, they discover what, if any, unique properties the nanoscale material exhibits; and third, they find practical applications for these unique properties. This process can present potential high levels of exposures to nanomaterials that have properties unknown to the researcher and laboratory workers. It may also inadvertently create materials that could be very dangerous. And, in almost all cases, the engineered nanoscale materials have never existed before and their properties and how the body and the environment will react to them are completely unknown.

Given the unique properties of nanomaterials, the safety protocols applied for more common laboratory research may not be sufficient when handling nanoscale materials. Additionally, because of the iterative nature of the research, repeated exposures to nanoscale materials with unknown properties may create a health issue for researchers, lab technicians and graduate or post-doctoral students who are working with these particles.

Research laboratories can take reasonable and sensible steps to reduce exposures to nanoscale materials while research is being conducted. The technology exists to characterize, study, and determine if a nanoscale material will adversely affect human or environmental health.

Recent incidents at college and university labs have heightened the awareness of safety issues and potential liability arising from activities at these labs. In January 2009, the Occupational Safety and Health Administration (OSHA) cited a university in New York for nine alleged serious safety violations and assessed a proposed penalty of $56,700.[15] OSHA's actions were in response to an August 6, 2008 incident at the university in which a lab employee was injured. The employee was servicing a pressurized diagnostic device when it exploded.[16] OSHA cited the university for deficiencies in equipment design, improper equipment installation, failure to have qualified personnel work on the equipment, failure to utilize personal protective equipment, and failure to evaluate the work area for hazards.[17]

In May 2009, a California university was fined $31,875 by the California Division of Occupational Safety and Health (Cal/OSHA) for

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15. Press Release, Occupat'l Safety and Health Admin., *U.S. Department of Labor's OSHA issues 9 serious citations to University of Rochester laser lab following August 2008 accident that seriously injured worker* (Jan. 22, 2009), http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id =17354.

16. *Id.*

17. *Id.*

alleged violations related to an incident on December 29, 2008, that resulted in the death of a laboratory assistant weeks after the incident.[18] Cal/OSHA cited the university for violations related to the school's hazardous chemicals training, its workplace safety procedures, and its laboratory recordkeeping.[19] Cal/OSHA has also initiated a criminal investigation regarding the incident,[20] and the case has drawn the attention of workplace accident and wrongful death attorneys.[21]

In January 2010, a student was seriously injured in an accident in a chemistry department laboratory at a university in Texas when a mixture of nickel hydrazine perchlorate exploded.[22] This incident is unique because it triggered not only an internal investigation, but also an investigation by the Chemical Safety Board (CSB).[23] The investigation represents the first time that the CSB has investigated an accident in an academic research lab.[24] CSB's chairman, John Bresland, stated that, in addition to conducting an investigation of the incident itself, CSB will collect information on other laboratory accidents.[25] Based on an analysis of this information, CSB will determine whether a more detailed study of academic lab safety is warranted.[26] CSB's investigation is ongoing.[27]

In July 2010, the Texas university released a report that set forth a series of recommendations to improve laboratory safety at the university.[28] The recommendations will be implemented by a new, university-wide Research Safety Committee.[29] The report recommended that an external peer review

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18. Kim Christensen, *State Fines UCLA in Fatal Lab Fire*, L.A. TIMES, May 5, 2009, http://www.laimes.com/features/health/la-me-uclalab5-2009may05,0, 6665233.story.

19. *Id.*

20. Kim Christensen, *Cal/OSHA Chief to Oversee Criminal Investigation of Fatal UCLA Lab Fire*, L.A. TIMES, June 30, 2009, http://articles.latimes.com/2009/jun/30/local/me-ucla-burn30.

21. *See*, e.g., Fatal Explosion and Fire at UCLA Lab Results in Fine, LOS ANGELES INJURY LAWYER BLOG (May 12, 2009), http://www.los-angeles-injury-lawyer-blog.com/2009/05/fatal_explosion_and_fire_at_uc.html. In considering the potential for civil liability, a state college or university will need to consider the applicability of its state's sovereign immunity doctrine to its particular circumstances. This article does not address this issue.

22. Jeff Johnson, *University Lab Accident Under Investigation*, CHEM. & ENG. NEWS, (Jan. 20, 2010), *available at* http://pubs.acs.org/cen/news/88/i04/8804notw1.html.

23. *Id*.

24. *Id*.

25. *Id*.

26. *Id*.

27. *See* investigation status at http://www.csb.gov/investigations/detail.aspx?SID=90&Type=1&pg=1&F_All=y (last visited Apr. 4, 2011).

28. Jeff Johnson, *Texas Tech Overhauls Lab Safety*, CHEM. & ENG. NEWS, (July 23, 2010), http://pubs.acs.org/cen/news/88/i30/8830news7.html.

29. *Id*.

panel assess campus lab safety practices and advise the university on how these practices can be improved.[30]

While none of the incidents discussed above involved the manufacturing or use of nanomaterials in a college or university lab, the incidents do highlight the need for a college or university participating in nanomaterials research to evaluate its compliance with applicable state and federal occupational safety and health requirements.

I. POTENTIAL RISKS

Nanomaterials have unique characteristics and properties that distinguish them from materials produced or existing at the micro- or macro-scale. Examples of characteristics include greater catalytic efficiency, increased electrical conductivity, and improved hardness and strength.[31]

The same characteristics and properties that hold such promise for the future may also present environmental, health, and safety challenges. Because of their increased surface area and smaller dimensions,[32] nanomaterials present potential exposure issues to workers that must be addressed. Studies have shown that certain nanomaterials have the ability to pass through cell membranes or cross the blood-brain barrier in ways that larger scale materials cannot.[33] Inhaled nanoparticles may become lodged in the lung.[34] Studies have documented health impacts in rodents[35]

30. *Id*.

31. *Research on Environmental and Safety Impacts of Nanotechnology Before the H. Subcomm. On Research and Science Education* 110th Cong. 47–62 (Oct. 31, 2007) (statement by E. Clayton Teague, Dir. Of Nat'l Nanotechnology Coordination Ofc.), *available at* http://commdocs.house.gov/committees/science/hsy24464.000/hsy24464_0.htm.

32. David Williams, *Health Benefits and Risks of Products of Nanotechnology*, Taiwan International Conference on Bionano Science, Dec. 5–7, 2007.

33. *See, e.g.*, Dmitry I. Kopelevich et al., *Potential Toxicity of Fullerenes and Molecular Modeling of Their Transport across Lipid Membranes*, *in* NANOSCIENCE AND NANOTECHNOLOGY: ENVIRONMENTAL AND HEALTH IMPACTS, (V.H. Grassian, ed., 2008); Press Release, Cedars-Sinai Medical Center, *Cedars-Sinai "Nano-Drug" Hits Brain Tumor Target Found in 2001*, (Nov. 4, 2010), *available at* http://www.cedars-sinai.edu/About-Us/News/News-Releases-2010/Cedars-Sinai-Nano-Drug-Hits-Brain-Tumor-Target-Found-in-2001.aspx; NanoTrust, Austrian Academy of Sciences, *Can Nanoparticles End Up in the Brain?*, NANOWERK, (Dec. 8, 2010), http://www.nanowerk.com/spotlight/spotid=19339.php.

34. *See, e.g.*, Jessica P. Ryman-Rasmussen et al., *Inhaled Carbon Nanotubes Reach the Subpleural Tissue in Mice*, 4 NATURE NANOTECH. 747, 747–51 (2009).

35. *Id. See also*, Jürgen Pauluhn, *Subchronic 13-Week Inhalation Exposure of Rats to Multiwalled Carbon Nanotubes: Toxic Effects are Determined by Density of Agglomerate Structures, Not Fibrillar Structures*, 113 TOXICOL. SCI. 226, 226–42 (2010); David B. Warheit et al., *Comparative Pulmonary Toxicity Assessment of Single-wall Carbon Nanotubes in Rats*, 77 TOXICOL. SCI. 117 (2004); Günter Oberdörster et al., *Translocation of Inhaled Ultrafine Particles to the Brain*, 16 INHALATION TOXICOLOGY 437, 437–45 (2004); Chiu-Wing Lam et al, *Pulmonary Toxicity of Single-Wall Carbon Nanotubes in Mice 7 and 90 Days after Intratracheal*

and fish.[36]

The health, safety, and environmental implications of nanomaterials must be addressed in order to achieve the promise of nanotechnology. Colleges and universities engaged in the research and development of nanomaterials or the production, processing, distribution and disposal of nanomaterials need to identify and address the potential risks of these operations.

Workplace exposures, if not mitigated, can occur at greater levels than that seen in the general environment due to higher concentrations and amounts of nanomaterials and higher exposure levels[37] and frequencies.[38] The need to assess and, where necessary, address these risks is an essential element of a college's or university's risk management program, but it is also required under federal and, in some cases, state law.

A college or university engaged in the research, development, manufacturing, processing, distribution or disposal of nanomaterials must ensure compliance with federal law and the associated regulations. Failure to do so can result in the imposition of administrative,[39] civil[40] or criminal penalties;[41] increased exposure to potential toxic tort liability;[42] and a potential threat to the viability of the college or university and the nanotechnology industry as a whole.[43]

II. REGULATIONS

Under the Occupational Safety and Health Act (the "Act"), "employers" must comply with the requirements of the Act and the regulations promulgated thereunder by OSHA.[44] An "employer" is defined as "a

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Instillation, 77 TOXICOL. SCI. 126, 126–34 (2004).

36. Zheng-Jiang Zhu, *Surface Properties Dictate Uptake, Distribution, Excretion, and Toxicity of Nanoparticles in Fish*, 6 SMALL 2261, 2261–65 (2010); Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENVTL. HEALTH PERSP. 1058, 1062 (2004).

37. Envtl. Prot. Agency, Nanotechnology White Paper 43 (2007).

38. *Id*.

39. *See, e.g.*, 29 C.F.R. § 1903.15 (2010) (proposed administrative penalties for OSHA violations).

40. *See, e.g.*, 29 U.S.C. § 666(a)-(d), (i) (2006) (statutory civil penalties for OSHA violatons).

41. *See, e.g.*, 29 U.S.C. § 666(e)-(g) (2006), 18 U.S.C. § 3571 (2006) (statutory criminal penalties for OSHA violations).

42. *See* John C. Monica, Jr. et al., *Preparing for Future Health Litigation: The Application of Products Liability Law to Nanotechnology*, 3 NANOTECH. L. & BUS. 54–63 (2006); Ronald C. Wernette, *Nanoparticles: The New Frontier For Product Liability Mass Tort and Class Action Claims*, 25 TOXICS L. REP. 1196, 1196-1202 (2010).

43. *See* Kristen Kulinowski, *Nanotechnology: From "Wow" to "Yuck"?*, 24 BULL. OF SCI., TECH. & SOC'Y 13, 18 (2004).

44. 29 U.S.C. § 654(a) (2006); 29 C.F.R. § 1903.1 (2010).

person engaged in a business affecting commerce who has employees, but does not include the United States or any State or political subdivision of a State."[45] Given the broad definition of "commerce,"[46] private colleges and universities must comply with federal occupational safety and health requirements. The Act and OSHA's regulations impose general and specific requirements on colleges and universities.

A. The General Duty Clause

The General Duty Clause imposes on a college or university a duty to provide each of its employees "a place of employment . . . free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."[47] Although courts have ruled that the Act and its accompanying regulations should be construed to afford the broadest possible protection to workers,[48] the purpose of the Act is to provide a satisfactory standard of safety, not to guarantee absolute safety.[49] Further, a college or university is entitled to fair notice of prohibited or required conduct.[50] The question of whether a hazard is recognized goes to the knowledge of the college or university, or in the absence of actual knowledge, to the standard of knowledge in the industry.[51] At the same time, a college or university cannot ignore the presence of an obviously hazardous condition by asserting that its industry is ignorant of such

45. 29 C.F.R. § 1910.2(c) (2010).

46. 29 U.S.C. § 652(3) (2006); 29 C.F.R. § 1910.2(e) (2010) ("Commerce means trade, traffic, commerce, transportation or communication among the several States, or between a State and any place outside thereof, or within the District of Columbia, or a possession of the United States (other than the Trust Territory of the Pacific Islands), or between points in the same State but through a point outside thereof").

47. 29 U.S.C. § 654(a)(1) (2006).

48. Universal Constr. Co. v. Occupat'l Safety and Health Review Comm'n, 182 F.3d 726, 729 (10th Cir. 1999); E & R Erectors, Inc. v. Sec'y of Labor, 107 F.3d 157, 160 (3d Cir. 1997).

49. Irving v. United States, 162 F.3d 154, 168 (1st Cir. 1998).

50. Crown Pacific v. Occupat'l Safety and Health Review Comm'n, 197 F.3d 1036, 1040 (9th Cir. 1999), Fluor Constructors, Inc. v. Occupat'l Safety and Health Review Comm'n, 861 F.2d 936, 941–942 (6th Cir. 1988).

51. Fluor Constructors, 861 F.2d at 942; *see also* McKie Ford, Inc. v. Sec'y of Labor, 191 F.3d 853, 856 (8th Cir. 1999); Martin v. American Cyanamid Co., 5 F.3d 140, 146 (6th Cir. 1993); Corbesco, Inc. v. Dole, 926 F.2d 422, 427–428 (5th Cir. 1991). The industry standard raises an interesting issue in the context of nanotechnology, which currently does not technically fall within the scope of an "industry," as contemplated by the Standard Industrial Classification system. Nanotechnology is an approach to manufacturing which has applications across industries. This presents the possibility of different industry standards being applicable to the manufacture of products from the same nanomaterial. Given at least the possibility that two industries may face similar exposure issues but operate with different levels of sophistication with respect to the handling of the nanomaterials, such an outcome would be less than optimal.

hazards.[52]

An additional issue is whether there is a technologically and economically feasible method for correcting the hazard. The courts have addressed technological and economic feasibility in the context of the General Duty Clause to a limited degree, finding that an employer must take all feasible steps to abate or prevent a hazardous condition that those in its industry would recognize as being hazardous.[53]

Failure to comply with the General Duty Clause can result in significant consequences, including administrative, civil, or criminal penalties.[54] The failure can also expose an entity to liability for any personal injuries that may be attributable to the failure.

Given that the General Duty Clause is, at its heart, based on the actions that would be taken by a "reasonable college or university," a college or university lab manufacturing or utilizing nanomaterials would be well-served by conducting a survey of the applicable information that is available regarding the behavior of the particular nanomaterials in use at its laboratories, the toxicological effects associated with exposure to the materials, and any engineering controls, administrative controls, and personal protective equipment that can be utilized to address any hazards that the materials may present. Given the evolving nature of nanotechnology and our knowledge of its effects, this process will need to be implemented iteratively. A one-time assessment by a college or university of its nanomaterial labs will likely not be sufficient to meet the requirements of the General Duty Clause.

B. Special Duty Clause

In addition to the general duty placed on colleges and universities to provide a safe workplace, the Act imposes a specific obligation to comply with all occupational safety and health standards promulgated under the Act.[55] Under this provision, OSHA is not required to prove the existence of an actual hazard or an actual exposure to a hazard. Conversely, strict compliance with an occupational safety and health standard will not

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52. *See* Safeway, Inc. v. Occupat'l Safety & Health Review Comm'n, 382 F.3d 1189, 1195 (10th Cir. 2004).

53. Banovetz v. King, 66 F. Supp. 2d 1076, 1084 (D. Minn. 1999). For a discussion of technological and economic feasibility in the context of standards promulgated through the rulemaking process, *see* Pub. Citizen Health Res. Grp. v. U.S. Dept. of Labor, 557 F.3d 165 (3d Cir. 2010); Kennecott Greens Creek Min. Co. v. Mine Safety and Health Admin., 476 F.3d 946 (D.C. Cir. 2007); Chao v. Gunite Corp., 442 F.3d 550 (7thCir. 2006); Color Pigments Mfrs. Ass'n, Inc. v. Occupat'l Safety and Health Admin., 16 F.3d 1157, 1161–64 (11th Cir. 1994); Am. Iron & Steel Inst. v. Occupat'l Safety and Health Admin., 939 F.2d 975 (D.C. Cir. 1991); Assoc. Builders and Contractors, Inc. v. Brock, 862 F.2d 63 (3d Cir. 1988); Nat'l Cottonseed Prods. Ass'n of Va. v. Brock, 825 F.2d 482 (D.C. Cir. 1987).

54. 29 U.S.C. § 666 (2006).

55. 29 U.S.C. § 654(a)(2) (2006).

insulate a college or university from liability for failing to comply with the General Duty Clause, where a recognized hazard has not been adequately addressed by the applicable specific standard.[56]

Although there are not occupational safety and health standards specifically designed to address potential risks from handling nanomaterials, colleges and universities should be aware of OSHA regulations that are generally applicable to research and development, manufacturing, processing, distribution or disposal operations which may have nano-specific implications. Regulations of particular interest include those that relate to hazard communication; engineering controls; administrative controls; and personal protective equipment.[57] These issues were central to the federal and state investigations that occurred following the lab incidents at the universities in New York and California.

C. Laboratory Requirements

OSHA has promulgated requirements specifically addressing occupational exposures to hazardous chemicals in laboratories.[58] With limited exceptions,[59] these requirements supersede all other OSHA health standards set forth in 29 C.F.R. Part 1910, Subpart Z.[60]

To establish the applicability of these provisions to a college's or university's operations, the institution must determine if its operations are conducted in a "laboratory" and if the operations involve the use of "hazardous chemicals." A "laboratory" is a "workplace where relatively small quantities of hazardous chemicals are used on a non-production basis."[61] A "hazardous chemical" is a "chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees."[62] In the context of nanomaterial operations, the hazardous chemicals could include the nanomaterial itself or the chemicals used to produce the nanomaterial.

"Laboratory use of hazardous chemicals" means the "handling or use of such chemicals in which all of the following conditions are met:

(i) Chemical manipulations are carried out on a 'laboratory scale';[63]

56. 29 C.F.R. § 1910.5(f) (2010).

57. For an in-depth discussion of these requirements, *see* Paul C. Sarahan, *Nanotechnology Safety: A Framework for Identifying and Complying with Workplace Safety Requirements*, 5 NANOTECH. L. & BUS., 191, 191–205 (2008).

58. 29 C.F.R. § 1910.1450 (2010).

59. 29 C.F.R. § 1910.1450(a)(2), (3) (2010).

60. 29 C.F.R. § 1910.1450(a)(2) (2010).

61. 29 C.F.R. § 1910.1450(b) (2010).

62. *Id*.

63. *Id*. "Laboratory scale" is "work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and

(ii) Multiple chemical procedures or chemicals are used;

(iii) The procedures involved are not part of a production process,[64] nor in any way simulate a production process; and

(iv) 'Protective laboratory practices and equipment'[65] are available and in common use to minimize the potential for employee exposure to hazardous chemicals."[66]

Colleges and universities conducting operations that fall within the "laboratory" provisions of 29 C.F.R. § 1910.1450 must comply with applicable permissible exposure limits (PELs); develop and implement a chemical hygiene plan; review and evaluate the effectiveness of the chemical hygiene plan at least annually, and update it as appropriate; provide information and training to its employees regarding the hazards of the chemicals present in their work area; and ensure that hazardous chemicals are properly labeled and that material safety data sheets are maintained and readily accessible, among other requirements.[67]

If the college's or university's lab operations are carried out at a commercial, rather than laboratory scale, the lab is subject to the broader OSHA health standards set forth in 29 C.F.R. Part 1910, Subpart Z, addressing toxic and hazardous substances. These include requirements applicable to specific chemical substances. In addition, these regulations establish permissible exposure limits, employee access to exposure and medical records, and comprehensive hazard communication and labeling requirements.

State colleges and universities, by definition, are established and operated by the state. Under section 652 of the Act, state colleges and universities are excluded from the definition of "employer." Under this provision, state colleges and universities are not subject to federal enforcement of standards[68] unless the state has obtained OSHA's approval

safely manipulated by one person." It excludes workplaces whose function is to produce commercial quantities of materials. *Id.*

64. *Id*. OSHA has issued interpretations regarding activities that are "part of a production process." The activities include most quality control/quality assurance activities and pilot plants. *See, e.g.*, Memorandum from Patricia K. Clark, Director of OSHA's Directorate of Compliance Programs, to John B. Miles, Jr., Regional Administrator regarding Requests for Interpretation of the Laboratory Standard, (Feb. 8, 1991, as corrected on Oct. 29, 2002), http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=20190 (last visited Jan. 24, 2011).

65. "Protective laboratory practices and equipment" are those procedures, practices, and equipment accepted by laboratory health and safety experts as effective, or that the employer can show are effective, in minimizing the potential for employee exposure to hazardous chemicals. *Id.*

66. *Id*.

67. 29 C.F.R. § 1910.1450(c)–(j) (2010).

68. Letter from Richard Fairfax, Director, Directorate of Enforcement Programs, OSHA, to Dick Bartosh, Environmental, Health and Safety Officer, University of

to assume enforcement of the federal standards.

Under the Act, to assume responsibility for the development and enforcement of occupational safety and health standards regarding an issue with respect to which a federal standard has been developed, the state must submit a state plan to OSHA for its review and approval.[69] The state's plan must "be at least as effective in providing safe and healthful employment and places of employment" as the standards established by OSHA.[70] To be approved, state plans must also include "an effective and comprehensive occupational safety and health program" applicable to all employees of the state's public agencies and its political subdivisions,[71] which is as effective as the standards contained in the approved plan. Twenty-one states[72] have submitted and received approval of state plans that address private and public sector occupational safety and health requirements.[73] Public colleges and universities located in states with OSHA-approved state plans are therefore subject to the State Occupational Safety Standards. A state's plan typically adopts all of OSHA's standards, with the exception of specific identified sections.[74] In these twenty-one states, the applicable requirements with which a state college or university must comply are substantially equivalent to the federal OSHA requirements.

Similarly, some states have adopted federally-approved programs covering solely its state and local employees. These states include New York, Connecticut, and New Jersey. Each of these states has adopted regulations that are consistent with those established by OSHA. Public colleges and universities in these states must comply with the applicable state requirements and are subject to inspection and enforcement by the state authorities. Because these states have adopted the federal requirements, as applied to its public sector employees, a public college's or university's analysis of its compliance requirements would follow the analysis for a private college or university set forth earlier in this article.

Twenty-nine states have not chosen to seek approval of a state plan to

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Wisconsin at Stevens Point (Oct. 11, 2006), http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=25536 (last visited Jan. 24, 2011). *See also* 29 C.F.R. § 1975.5(b)–(e) (setting forth tests and factors for determining whether an entity is a subdivision of the state, including State University Boards of Trustees as an example of a subdivision of the state).

69. 29 U.S.C. § 667(b) (2006).

70. 29 U.S.C. § 667(c)(2) (2006).

71. 29 U.S.C. § 667(c)(6) (2006); 29 C.F.R. § 1902.3(j) (2010).

72. These include Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington and Wyoming.

73. 29 C.F.R. § 1952 (2010).

74. *See, e.g.*, 29 C.F.R. § 1952.90 (2010) (South Carolina adopts OSHA's standards with the exception of 29 C.F.R. §§ 1910.13–1910.16).

address private sector occupational, safety, and health requirements.[75] OSHA is responsible for enforcing these requirements with respect to private colleges and universities in these states. Private colleges and universities within these states are subject to OSHA's jurisdiction, and the compliance requirements for these institutions would follow the analysis for a private college or university set forth earlier in this article. Because the Act specifically excludes coverage of public sector employees, public sector colleges and universities in these states are not subject to OSHA's jurisdiction.[76] However, some of these states have developed occupational safety standards that are applicable to their respective state colleges and universities.[77]

D. NIOSH's Recommended Exposure Limits

In April 2011, the National Institute for Occupational Safety and Health (NIOSH) issued recommended occupational exposure limits for fine and ultrafine, or nanoscale, titanium dioxide (TiO_2).[78] TiO_2 is a noncombustible, white, crystalline, solid, odorless powder, which is utilized in both fine and nanoscale forms in many products, including paints and varnishes, cosmetics, plastics, paper, and food as an anti-caking or whitening agent. Colleges or universities with fine and nanoscale[79] TiO_2 operations must consider the implications arising from this recent publication.

Based on its analysis, NIOSH has recommended airborne exposure limits of 2.4 mg/m^3 for fine TiO_2 and 0.3 mg/m^3 for nanoscale TiO_2, as time-weighted average (TWA) concentrations for up to 10 hr/day during a 40-hour work week. NIOSH's review of current scientific evidence led it to conclude that the surface area of the TiO_2 particles is a critical risk factor for occupational exposure to TiO_2. Nanoscale TiO_2 particles have a larger surface area and are thus of greater concern, according to NIOSH's review.

Unlike OSHA's PELs, this Recommended Exposure Limit (REL) is not a regulatory standard. NIOSH's publication of the REL, however, does carry significant weight and has implications for potential liability if the

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75. 29 C.F.R. § 1952 (2010).

76. 29 U.S.C. § 652(5) (2006).

77. *See e.g.*, GA. CODE ANN. § 45-22-1 et seq. (West 2009); MASS. GEN. LAWS ANN. ch. 111F (West 2009); OHIO REV. CODE ANN. § 4167 (West 2009); OKLA. STAT. ANN. tit. 40 (West 2009); 35 PA. STAT. ANN. § 7302 et seq. (West 2009); TEX. HEALTH & SAFETY CODE ANN. §§ 502.001–502.020, 506.001–506.017 (Vernon 2007).

78. NAT'L INST. FOR OCCUP'L SAFETY & HEALTH, CURRENT INTELLIGENCE BULLETIN 63: OCCUPATIONAL EXPOSURE TO TITANIUM DIOXIDE (2011) http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf (last visited June 1, 2011).

79. NIOSH has defined ultrafine TiO2 as having a primary particle diameter of <100 nanometers. *Id*. Ultrafine TiO2 fall within the definition of nanoscale materials.

limit is exceeded.

In addition, late last year, NIOSH initiated a public comment process on its draft Current Intelligence Bulletin Occupational Exposure to Carbon Nanotubes and Nanofibers.[80] Relying on several animal studies that "consistently show that relatively low mass doses of CNT are associated with early-stage adverse lung effects in rats and mice," including pulmonary inflammation and fibrosis, NIOSH has proposed a REL of 7 $\mu g/m^3$ elemental carbon as an eight-hour TWA respirable mass airborne concentration.[81]

Although the REL is proposed to be set at the lowest airborne CNT and carbon nanofiber (CNF) concentration that can be accurately measured by NIOSH procedures, this level is above that at which NIOSH suggests that an excess risk of adverse lung effects is predicted. Therefore, in addition to proposing an REL, NIOSH is suggesting recommended practices for employers and employees to further minimize exposure to airborne concentrations of CNT and CNF.[82]

Although NIOSH's RELs for CNTs, CNFs are in draft form at this time, it is likely that such recommended limits would have some persuasive weight in litigation arising from occupational exposure to such materials.

III. ASSESSMENTS

When a college or university decides to conduct an assessment, it is important to analyze the nature of its facility's operations to ensure that all applicable regulatory issues are considered. In doing so, the college or university should consider the appropriate scope of the assessment. A smaller operation may choose to assess all of its operations, particularly if an assessment has not been conducted previously. A college or university with larger operations, or one with operations that have been previously assessed, may consider assessing a particular aspect of its operations. The college or university may also conduct an assessment to determine its compliance with particular provisions of the applicable state and federal regulations. Additionally, the college or university should consider any points from which materials or pollutants could be released to the environment to assist in evaluating potential exposures to employees, facility visitors, and adjacent or nearby properties.

Once a college or university has analyzed the nature of the facility to be assessed, the points from which a release could occur, and the intended

80. NAT'L INST. FOR OCCUP'L SAFETY & HEALTH, CURRENT INTELLIGENCE BULLETIN: OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBERS (Draft) (2010), http://www.cdc.gov/niosh/docket/review/docket161A/pdfs/carbonNanotubeCIB_PublicReviewOfDraft.pdf (last visited Jan. 24, 2011).

81. *Id*.

82. CURRENT INTELLIGENCE BULLETIN: OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBERS, *supra* note 78.

scope of the assessment, the college or university and any consultant involved in the assessment should determine the potentially applicable requirements that fall within the scope of the assessment. In compiling the list of potentially applicable requirements, the assessment team should approach the task inclusively. The assessment team can always narrow the list based on a more in-depth analysis conducted as part of the assessment process. The assessment team is less likely to consider additional requirements to be added to the list as it goes through the assessment process. Being inclusive at the front-end of the project will provide greater certainty that all potential issues have been identified and evaluated.

The assessment should be developed and performed under an applicable audit act or policy, or under the attorney-client privilege. The assessment team must consider, prior to the initiation of the assessment, whether the assessment will be performed under an audit act or policy. This decision will allow the assessment team to ensure that it meets the applicable requirements of the act or policy to be used. Each act or policy is structured differently and has different advantages and disadvantages that must be considered in light of the college's or university's objectives.

If the applicable act provides an evidentiary privilege, or if the assessment is conducted under the attorney-client privilege, the assessment team should ensure that information created, gathered or obtained during the course of the assessment is not voluntarily disclosed to persons outside the scope of the applicable privilege, or the privilege can be waived. If disclosure is required, the college or university should do so under the terms of a confidentiality agreement, where appropriate.

Upon completion of the assessment, compliance issues should be identified and included in an assessment report. As part of this process, the college or university should consider and develop proposed corrective actions to address any issues identified in the assessment and a proposed timeframe for the completion of each corrective action. The efforts of the college or university to implement corrective actions in a timely manner will improve workplace conditions and further minimize its potential liability.

In the context of nanomaterial operations, a college or university should consider an iterative assessment process, with an assessment being conducted semi-annually or annually, on all or a portion of the college's or university's nanomaterial operations, depending on the extent of such operations. For institutions with numerous nanomaterials operations, the assessment team may consider using a risk analysis to identify a subset of operations that will be included in the assessment. One consideration in such a risk analysis may be the extent to which an operation selected to be included in the assessment is representative of other operations at the college or university, such that the results of the assessment can be applied more broadly.

An iterative assessment approach is appropriate because of the evolving nature of the technology, the current knowledge of potential risks, and the availability of protective measures to address these potential risks. The performance of periodic assessments will improve the college's or university's ability to ensure that it is complying with the state and federal occupational safety and health requirements, and is aware of developments related to nanotechnology processes, risks and protective measures. Through such a process, the college or university can provide working conditions that meet its obligations to its employees and to state and federal regulatory authorities.

Such an approach is consistent with the standards of the American Society for Testing and Materials (ASTM). ASTM International published a *Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings* in October 2007.[83] This guidance is based on the principle that occupational exposures to unbound nanomaterials "should be minimized to levels that are as low as is reasonably practicable."[84] Through this guidance, ASTM International recommends the following:

• The development of a formal written management policy based on this "control principle";

• Formal designation of responsibilities within the organization for developing and implementing a risk assessment and minimization program; (the "Program");

• The development of training regarding the Program;

• The development of record keeping and record retention procedures to document the implementation of the Program; and

• A periodic review of the Program.[85]

A college or university manufacturing, processing, distributing, or disposing of nanomaterials can position itself to ensure workplace safety, and prevent or limit liability associated with such activities by taking the following steps:

(1) Determine what nanomaterials are used or are present at the facility. This step is particularly important for facilities that are utilizing nanomaterials that have been manufactured elsewhere.

(2) Determine the composition, characteristics, concentrations, volume, and properties[86] of the nanomaterials, and identify any exposure

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83. ASTM Int'l, *Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings*, *in* ANNUAL BOOK OF ASTM STANDARDS Vol. 14.02 1109–1132 (2009).

84. *Id.* at 1111.

85. *Id.* at 1111–12.

86. Relevant properties include size and size distribution; shape; agglomeration state; biopersistence, durability and solubility; surface area; porosity; surface

pathways.[87] Research and testing by internal and external scientists may be necessary.[88]

(3) Review existing scientific studies relevant to the specific nanomaterials in use, as well as those that have similar compositions characteristics, properties, and exposure pathways. As part of this review, survey facilities engaged in similar operations to determine potential risks those facilities have identified.

(4) Determine the potential exposure risks associated with the nanomaterials that are being handled.

(5) Analyze the facility's processes to determine the potential points of releases, discharges, or emissions. The facility should consider material receipt and unpacking; manufacturing and finishing processes; lab operations; storage, packaging, and shipping; waste management; maintenance and housekeeping; and potential upset events.[89]

(6) Identify the local, state, and federal regulatory requirements applicable to the facility's operations.

(7) Identify and evaluate available engineering controls that can address potential releases of, or exposures to, the nanomaterials in use at the facility. As part of this process, survey facilities engaged in similar operations to identify any engineering controls in use.

(8) Identify and evaluate available administrative controls that can address potential releases of, or exposures to, the nanomaterials in use at the facility. As part of this process, survey facilities engaged in similar operations to identify any administrative controls in use.

(9) Identify and evaluate available personal protective equipment that can address potential releases of, or exposures to, the nanomaterials in use at the facility. As part of this process, survey facilities engaged in similar operations to identify any personal protective equipment in use.

(10) Identify and implement appropriate engineering controls, administrative controls, and personal protective equipment to be used at the facility.

(11) Establish standard procedures to prevent upset events and to respond to such events, should they occur.

(12) Establish standard operating procedures to ensure compliance with regulatory requirements and the appropriate and effective use of the engineering controls, administrative controls, and personal protective equipment.

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chemistry; trace impurities and contaminants; chemical composition; physical properties; and crystallinity. *Id*. at 1113.

87. Potential exposure pathways include inhalation, ingestion, and dermal contact, including eyes and mucus membranes. The most common exposure route is expected to be by inhalation. *Id*. at 1114.

88. Monica, *supra* note 42, at 63.

89. ASTM Int'l, *supra* note 83, at 1115.

(13) Communicate to the employees the results of the risk assessment and the standard operating procedures to be used to minimize the risks identified.

(14) Develop and provide training to the employees. Employees should be trained prior to their initial assignment to a nanomaterials work area. The training should be repeated on a periodic basis.

(15) Conduct periodic assessments of the facility's operations to test its regulatory compliance and the appropriate and effective use of the engineering controls, administrative controls, and personal protective equipment. The assessments should be performed under available state or federal audit programs and policies,[90] or under the attorney-client privilege.

(16) Establish or review the facility's records retention policy and system to ensure that appropriate documentation is maintained and to demonstrate that the facility has appropriately identified and addressed the potential risks from its nanomaterials operations. The facility's completion of each of the steps discussed above should be appropriately documented.

(17) Develop a system to periodically review the analysis set forth above to ensure that the information is current and that the decision-making is valid and appropriately documented. The rapidly-evolving development of nanotechnology and our knowledge of its potential effects necessitates an iterative process.

(18) Monitor any regulatory activities pending or under consideration at the local, state, and federal regulatory agencies.

IV. CONCLUSION

Nanotechnology's potential for incredible advances in a wide variety of industries is clear. Much of the groundwork for these advances is being conducted at colleges and universities across the United States. The success of these efforts is critical to the economic and technological success of the United States.

An increasing number of scientific studies are indicating that exposure to some nanomaterials under some conditions could pose human health risks. The first indication of the effects of such exposure will be seen in the workplace, where exposures, if not mitigated, can occur at greater levels than that seen in the general environment due to higher concentrations and amounts of nanomaterials and higher exposure levels and frequencies.

Because of the critical role being played by colleges and universities in the research and development of nanomaterials, college and university laboratories could be among the first workplaces in which the effects of

90. *See e.g.*, Final Policy Concerning the Occupational Safety and Health Administration's Treatment of Voluntary Employer Safety and Health Self-Audits, 65 Fed. Reg. 46,498 (July 28, 2010); Texas Environmental, Health and Safety Audit Privilege Act, TEX. REV. CIV. STAT. ANN. art. 4447cc (Vernon 2000); Oregon Occupational Safety Audit Act, OR. REV. STAT. § 654.101 (2009).

such exposure are identified. Colleges and universities should assess the nanomaterials operations ongoing on their campuses to ensure that appropriate protocols and procedures are in place to address the unique risks that can be posed by such materials. Through such an assessment, a college or university can ensure that it: (1) provides a safe workplace for its employees and students; (2) complies with applicable state and federal occupational safety and health requirements; and (3) minimizes potential workers compensation and toxic tort liability.

This article has provided a process that can be utilized to conduct such an assessment. Through the implementation of such a process, a college or university can document the nanomaterials in use in its laboratories, risk information applicable to such nanomaterials, and the protective measures implemented to address these risks. To increase the credibility of the assessment in the event of future litigation, it is recommended that the assessment team include third-party technical and legal consultants that have environmental, health, and safety expertise specific to nanomaterials. Finally, because of the rapidly-evolving development of both nanotechnology and the science regarding potential risks of nanomaterials, it is recommended that the assessments be conducted on a periodic basis to ensure that the information on which a college or university has designed its protocols and procedures is current and that its decision-making is valid and appropriately documented.