

Safety Culture in Life Sciences Laboratories: Through the Looking Glass

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Abstract: With all the talk recently about safety culture – it is easy to become confused as to what that really means. The term Safety Culture elicits a wide spectrum of responses in people when they are asked "so what is safety culture and what does it mean to you". This paper seeks to clear up that confusion and guide the reader on how to apply it to biosafety (and by extension biosecurity) in life sciences laboratories. After identifying the origins of the concept, safety culture is distilled down to three easily remembered behaviors and one foundational enabler. The role of culture as a lens through which regulations and tools (procedures and practices) are understood and applied, is then explained as an indispensable part of an integrated system to deliver reliable performance. Case studies are used to illustrate how these safety culture attributes, or lack thereof, can have profound impacts on organizations and the people within them. Lastly, the authors offer their proposed initial steps for biosafety professionals seeking to launch a safety culture improvement initiative. Creating a more easily understood description of safety culture, along with a personal and organizational safety construct through which to apply it, allows everyone to become involved and invested in a culture of safety. This leads to superior personal and organizational performance, safety, job satisfaction and efficiency of research.

Introduction: As evidenced in several recent investigations of high profile events in the field of biosafetyⁱ, the importance and necessity for a healthy “safety culture” has been identified as an essential element of any effectively functioning safety program. Unfortunately, the term “safety culture” appears to have as many definitions as people have perspectives. Even scholarly research has not coalesced down to a singular definition of what safety culture entailsⁱⁱ. This has left the professional biosafety community with a considerable challenge to help their client organizations understand, embrace and implement the concepts of safety culture in a meaningful and efficient way. As noted in a recent National Academies study, “[i]t is not enough to provide safe equipment, systems, and procedures if the culture of the organization does not encourage and support working safely in the laboratory.”ⁱⁱⁱ

Origins of Safety Culture: Although human behavior in the work environment has always been recognized as a contributor to safety performance, it was the Chernobyl nuclear reactor accident in 1986 which focused and attracted significant international attention to the importance of “safety culture”. On April 26, 1986, multiple explosions and a 14-day fire at the Chernobyl-4 nuclear reactor plant in Pripyat, Ukraine distributed radioactive contamination over hundreds of square miles and into airstreams around the world. A root cause of the accident was workers performing “tests” on the reactor systems while safety systems were bypassed, without a full understanding of what could go wrong, and within a management culture that did not practice accountability. A poor safety culture was identified as a factor contributing to the Chernobyl disaster by the International Atomic Energy Agency^{iv}. Since that time, “safety culture” has been indicted across multiple industries as a key contributor in other significant disasters (e.g., NASA/Challenger, Chemical/Bophahl, Oil/Piper Alpha).

Since the Chernobyl disaster, numerous papers, manuals and books have been authored on the subject of safety culture. A Google® internet search on “safety culture” returns nearly 88 million results; some scholarly works can run from 30 to 200+ pages in length.

For a safety professional, researcher or administrator, who is often already fully engaged with routine and programmatic activities, trying to make sense of all this information can be overwhelming. Especially frustrating is that sponsors and co-workers are looking for something simple and understandable; few of them are willing or able to sit for a multiple page exposé on all the different aspects of safety culture. This can also lead to the perception that safety culture is something that is being imposed on them, or is something that management has responsibility for.

An Understandable Model: At the risk of overly simplifying what is an admittedly rich topic for research, debate and analysis, the authors have distilled the subject of safety culture down into a set of four simple, easily remembered attributes that each of us can relate to on an emotional level. Using this simple model will allow you to have a meaningful conversation with any stakeholder in only a few short minutes. Readers are strongly encouraged, however, not to stop here in their research of safety culture. Selected references are provided at the end of the paper.

On an individual performance basis, and with extension to an organizational performance basis, Safety Culture can be distilled down into exhibiting the following three behaviors:

1. **Integrity** – I do the right thing even when no one is watching (e.g., follow procedures, wear required personal protective equipment). I also speak up when I see something that is not right.
2. **Curiosity** – Before commencing a task, I think about what could go differently than expected and implement methods to safely avoid, mitigate or recover from that situation.
3. **Humility** – I am human and will sometimes miss things, even obvious things. I openly accept the input of others who bring a fresh perspective (regardless of their position in the organization).

Added to these behaviors is one foundational enabler that is absolutely essential as the underpinning for the entire endeavor:

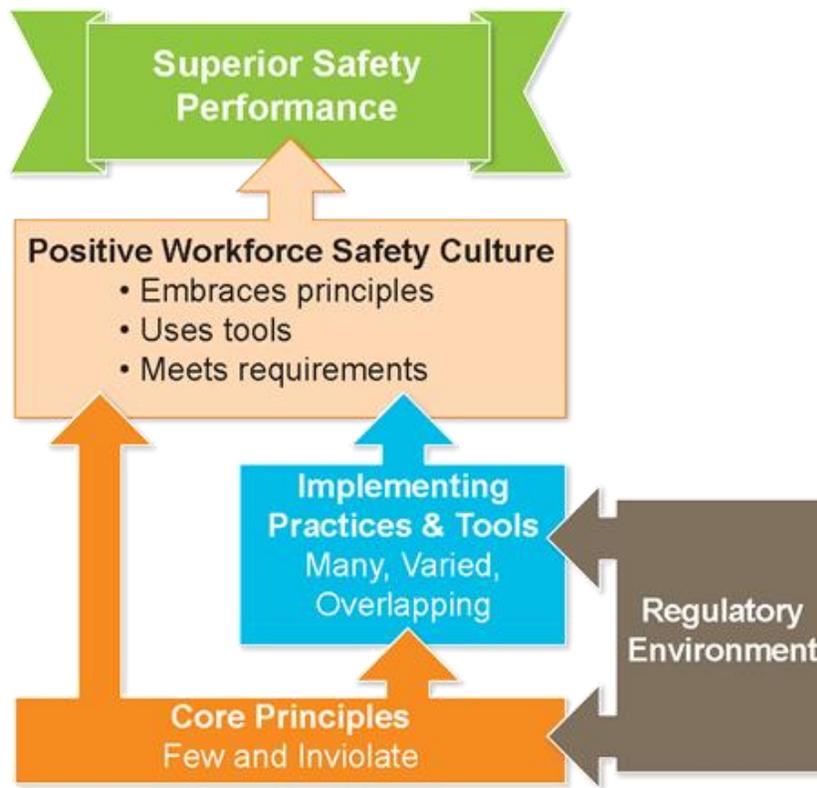
- **Leadership** – I take action to hold myself and those around me accountable. I inspire others to perform at a higher level than they currently do.

Without Leadership, all the rest is fragile and perishable. Every single act where authority is exercised to excuse misbehavior, press ahead blindly, or dismiss criticism erodes a safety culture just the same way as one “ah shucks” moment can erase a hundred “atta boys”. As will be described later in this paper, every major failure with a human contribution can usually be tied to lapses in one or more of the three safety culture behaviors and/or Leadership. To help remember these four key attributes, the authors suggest using the following mnemonic, “**I Can Help Lead**”.

Safety Culture’s Integrating Role: As long as humans are involved, safety culture will contribute to the performance of the organization. The graphic below was developed by the authors in a 2015 concept paper prepared for the U.S. National Institute for Occupational Safety and Health

(NIOSH). This graphic lays out the inter-relationship between Regulations, Core Principles, Tools & Practices, and Workforce Safety Culture as they contribute to getting research done safely and effectively (Superior Safety Performance).

- **Regulations** – cannot of themselves assure safety. Even by outlawing certain practices, materials or conditions, the opportunity remains that these controls may be misunderstood, worked around or ignored. However, regulations are the tools of governing bodies and will be used when offending organizations appear unwilling or unable to enact improvements of their own accord. Also, regulations are invariably backwards looking (usually in response to calamity) and so cannot be depended upon alone to provide an adequate envelope of safety for novel or new applications such as research. Conversely, the absence of regulations does not need to mean that the work being undertaken is unsafe, however the burden falls on the performers to protect themselves, the public and the environment.
- **Core Principles** – reflect the values of the individual and organization and frequently may be rooted in regulations (fair business practices and equal opportunity employment are examples). Such principles are often documented, sometimes not, but are always powerful influences on the workforce. For example, the US Department of Energy has codified eight guiding principles as essential to its safety management^v, these are typically reflected at each DOE site in policies, posters and training of various types. More importantly, however, is how the organization's leadership demonstrates, reinforces and gives substance to these principles. Leadership behaviors which are seen to be as consistent/inconsistent with one principle reinforce/undermine them all.
- **Practices & Tools** – are the methods by which work gets done. In and of themselves, they are typically inert and depend upon the human workforce to put them into motion. These tools are often the vehicle for regulatory implementation (e.g., procedures) and like procedures, cannot anticipate every situation or eventuality. Tools provide reliability and consistent quality when used properly within the bounds for which they were developed. Practices and tools may be made flexible enough to safely accommodate uncertainty and those situations for when the work is beyond the bounds normally encountered as long as appropriate core principles are also in place.
- **Workforce Safety Culture** – is the lens through which principles, practices, tools and regulations are understood and integrated for the accomplishment of work. It is this culture that helps workers and management decide how conflicting constraints (which are inevitable) get reconciled. In a healthy safety culture, core principles are overriding and provide a firm, shared basis for reconciliation decisions. In an unhealthy safety culture, core principles are not so honored and thus the basis upon which conflicts gets resolved becomes personality dependent and unpredictable.



- **Superior Safety Performance** – is the benefit associated with understanding and improving an organization’s safety culture. Studies show that the benefits of superior performance are not restricted to safety but also pay productivity dividends.^{vi} It’s worth remembering that in most cases, competing businesses are each operating under similar regulations and using the same basic tools and practices. The core principles leadership embraces and the culture the workforce displays are what distinguish the great from the adequate business performers.

Case Studies in Safety Culture: The attributes of safety culture can also be used as a lens to examine past events and understand how failures in safety culture can have significant and sometimes tragic consequences:

1. **CDC Anthrax (2014) Event:**^{vii} In June 2014, incomplete inactivation of Anthrax resulted in potentially viable *B. Anthraxis* being transferred from BSL-3 to BSL-2 and the possible exposure of staff at CDC. No infections occurred, however this event prompted a July 11, 2014 moratorium on any biological material leaving any CDC BSL-3 or BSL-4 laboratory. This event also contributed to an August 2014 White House directed work pause across all government labs working with select agents and toxins.

Safety Culture Analysis: Investigation by the CDC primarily faulted the lack of an approved, written study plan (**leadership**), but also identified other contributors:

- Researchers developing an alternative method for the identification of anthrax utilized an inactivation procedure from another lab based on a non-spore forming organism (**curiosity, humility**).
 - The researcher did not do a basic literature review (**curiosity**) and did not develop a written SOP or have the procedure reviewed (**integrity**). This led to a situation where what could go wrong was not fully vetted.
 - The organization was missing single point of accountability and an effective lessons learned program (**leadership**). There had been four previous events at CDC whose lessons learned could have factored into preventing this event: 2006 transfer of Anthrax to LLNL (anthrax inactivation issue) with corrective actions similar to what was put in place after this 2014 event; 2006 botulism (inactivation issue); 2009 brucella (wrong strain labeled and shipped); 2014 cross-contamination of high to low avian flu subsequently shipped to USDA (didn't follow procedures).
 - CDC demonstrated good response and accountability after reviews stemming from the White House pause (**leadership**).
2. **NIH/FDA Small-Pox Discovery (2014) Event:**^{viii} FDA was preparing to move out of an NIH lab building and on July 1, 2014, an FDA researcher opens a box in the facility cold storage room and discovers 327 glass vials which are not included in any inventories; six of which are labeled as “variola” (commonly known as smallpox). Subsequent testing by CDC confirms viable smallpox virus in two of the six vials. In August, the White House directs a standdown to “search and categorize” such materials across all federally funded laboratories. The U.S. House of Representatives staff memorandum concludes “Federal agencies must address cultural factors in addition to its policy and management efforts to ensure the effectiveness of its lab safety programs.”

Safety Culture Analysis: Investigation by the CDC, FBI and U.S. House of Representatives identifies the following information:

- FDA moved into NIH lab building in 1972 but labeling on the 327 glass vials dates from 1946-1964. The FDA researcher who will eventually find the samples started work in the labs in 1992 and remembers seeing these boxes when he first went to work, entering the cold room nearly every day (**curiosity, leadership**).
- Upon opening of the box and discovery of the vials, the incident is immediately reported (**integrity**).
- The vials, still in the boxes, are transported by hand to be put under NIH safekeeping. Clanking is heard from the box as they are being transported. Upon arrival for safekeeping, one of the non-variola vials is found to be breached. (**curiosity and humility**)
- As early as 1995, a senior NIH official was overheard saying they had “smallpox in the freezers” however investigation did not uncover this material (**leadership**).
- In 2011, NIH was cited for not having registered select agents when the material was received in 2007. This prompted a retraining event of principal investigators

(PIs) in 2012 during which two PIs self-declare other material (**integrity**). A sweep of anthrax labs finds more unregistered material but NIH only looks at their Anthrax labs (**curiosity**).

- Since 2011, cold rooms at NIH had a requirement to label all materials (owner, contact info) however this set of boxes remained unlabeled and thus “unowned”. (**leadership**)
- In 2012, the CDC Division of Select Agents and Toxins (DSAT) performs independent reviews and finds more unregistered materials. In a full sweep of all labs, all PIs attest to no unregistered material. Each PI however checked only their “own” materials and thus failed to identify the variola material (**curiosity, humility, leadership**).

3. **Dugway Proving Grounds (2015) Event:**^{ix} From 2004 – 2015, Dugway prepared 86 lots of inactivated anthrax for use by other research labs. In May 2015, one of the receiving labs cultures, finds and reports viable anthrax in a newly received lot. Investigation finds only 33 lots of inactivated anthrax still remaining at Dugway. Of those 33, 17 lot samples are found to contain viable spores. Samples from these 17 lots were received by labs in 50 states, three territories and nine foreign countries. In response, DoD issues a moratorium on all select agent and toxins work and CDC suspends Dugway’s Life Sciences Division certificate of registration for all select agents.

Safety Culture Analysis: A comprehensive Army review discovered a variety of safety culture issues going back a number of years.

- In 2007 a PI used an experimental vapor treatment (outside of standard operating procedure) to inactivate anthrax; of the five vials created, four were okay but one shows viable growth. The PI destroyed the bad vial and sent out the others – no retesting (**integrity, curiosity**). When another lab found viable spores, Dugway blamed cross contamination at the other lab and then downplayed the seriousness (**curiosity, humility**).
- As part of the corrective actions for past events, Dugway instituted a program for managers to review surveillance video footage from BSLs at least once a week to provide feedback to staff on performance – due to budget cutbacks and personnel reductions, managers reported they spent no time actually performing this function (**integrity/leadership**).
- During review by an outside agency, questionable practices were seen on video tapes [e.g., staff member drops petri dish (containing select agent) on floor during transport, picks it up, puts it back in BSL-3 cabinet, doesn’t wear PPE (**integrity**)]. The review also pointed out a lack of trending which would have identified a 20% failure rate on irradiations (**curiosity**).
- The Dugway staff, while aware of inactivation failures, did not relook at their base procedures but just re-irradiated the batches – leading to questions on quality control and lack of oversight (**leadership**). Later, independent environmental

surveys (not performed by Dugway even though required), found contamination on floors and surfaces outside containment (**integrity**).

- Given similar issues occurring the year before at CDC – there was no apparent response by Dugway to evaluate or take action associated with their own activities (**humility/curiosity/leadership**).

Conclusion: In this paper, the authors have described the importance of safety culture and four simple attributes for understanding and explaining it to others who don't have the time or interest in digesting the many pages of scholarly research on the subject. The mnemonic of “**I Can Help Lead**” will help readers remember these four attributes when caught away from their desk or reference materials. A simple model is also provided which logically demonstrates how safety culture is the lens, or “looking glass”, through which all regulations, tools, practices and principles are integrated to deliver superior organizational performance and its attendant benefits of excellence, efficiency, and safety in research.

For safety professionals, researchers, or administrators seeking understanding/improvements in their organization's safety culture, the following initial steps are recommended:

1. Select a simple conceptual model for use in explaining safety culture and its importance to others. There are many scholarly works on this subject and multiple models. Select a model that you can internalize and that “speaks” most effectively to the organization's particular needs.
2. Develop leadership support for understanding and improving the safety culture. This support probably includes resources but, more importantly, involves their commitment to adopt and support the Leadership behaviors necessary for a healthy safety culture.
3. Obtain a baseline assessment of the organization's existing safety culture. There are a variety of companies/tools, such as DuPont's Safety Perception Survey, that can assist with both conducting the assessment and benchmarking the results against a large database of industry survey results.

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In conducting the research for this paper, the authors examined the following Safety Culture references from various other industries. These are provided as potential sources for the interested reader:

“Safety Culture” Resources	Pages	Notes
U.S. OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION (OSHA)		
https://www.osha.gov/SLTC/etools/safetyhealth/mod4_factsheets_culture.html		Several web based references and 26 suggested individual improvement areas. No unified safety culture model is offered.
CHEMICAL		
American Institute of Chemical Engineers (AIChE) Center for Chemical Process Safety website, http://www.aiche.org/ccps		55 citations for books, articles, videos, and presentations on the subject of “Human Factors & Culture”
AEROSPACE		
NASA-HDBK-9709.24, <i>NASA Safety Culture Handbook</i> , November 23, 2015	34	Based upon Dr. James Reason’s safety culture model.
Safety Culture Model as described in the book <i>Managing the Risks of Organizational Accidents</i> , by J. Reason and J. Ashgate, 1997	252	An Informed Culture (aka Safety Culture) is defined as the integration of four other cultures (Reporting Culture, Just Culture, Flexible Culture, and Learning Culture)
NUCLEAR		
INPO 12-012, <i>Traits of a Healthy Nuclear Safety Culture</i> , Institute of Nuclear Power Operations (INPO), December 2012	12	Ten primary traits organized into three categories
IAEA Safety Report Series No. 83, <i>Performing Safety Culture Self-assessments</i> , June 2016	157	Designed to help organizations self-assess “safety culture” and understand how to use the results
US Department of Energy directives on Nuclear Safety, Integrated Safety Management, and Safety Conscious Work Environment. http://energy.gov/ehss/integrated-safety-management-safety-culture-resources	200+	An interwoven web of directives which all speak to safety culture or attributes thereof

ⁱ Please see endnotes vii, viii, ix

ⁱⁱ Technical Report ARL-02-3/FAA-02-2. *A Synthesis of Safety Culture and Safety Climate Research*, by Weigmann, Zhang, Thaden, Sharma and Mitchell, Aviation Research Lab, Institute of Aviation, University of Illinois at Urbana-Champaign, June 2002

ⁱⁱⁱ Safe Science: Promoting a Culture of Safety in Academic Chemical Research (2014), Board on Chemical Sciences and Technology, <http://dels.nas.edu/Report/Safe-Science-Promoting-Culture/18706?bname=bcst>, 2014.

^{iv} INSAG-7, The Chernobyl Accident: Updating of INSAG-1, A Report by the International Nuclear Safety Advisory Group, International Atomic Energy Agency, 1992, http://www-pub.iaea.org/MTCD/publications/PDF/Pub913e_web.pdf

^v U.S. Department of Energy Policy DOE P 450.4A, *Integrated Safety Management Policy*, April 25, 2011, <https://www.directives.doe.gov/directives-documents/400-series/0450.4-APolicy-a>

^{vi} National Safety Council, *The Business Case for Investment in Safety*, 2013
<http://www.nsc.org/JSEWorkplaceDocuments/Journey-to-Safety-Excellence-Safety-Business-Case-Executives.pdf>

^{vii} Report on the Potential Exposure to Anthrax, July 11, 2014, U.S. Centers for Disease Control and Prevention, https://www.cdc.gov/about/pdf/lab-safety/final_anthrax_report.pdf

^{viii} Supplemental Memorandum: Committee Investigation on the 2014 Discovery of Smallpox Vials at the National Institutes of Health, Bethesda, Maryland Campus, April 19, 2016, Majority Staff, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, <http://docs.house.gov/meetings/IF/IF02/20160420/104823/HHRG-114-IF02-20160420-SD003.pdf>

^{ix} U.S. Army, AR 15-6 Investigation Report – Individual and Institutional Accountability for the Shipment of Viable *Bacillus Anthracis* from Dugway Proving Ground (Unclassified), December 17, 2015, <https://assets.documentcloud.org/documents/2691592/Dugway-Proving-Ground-Anthrax-Shipment-AR-15-6.pdf>