

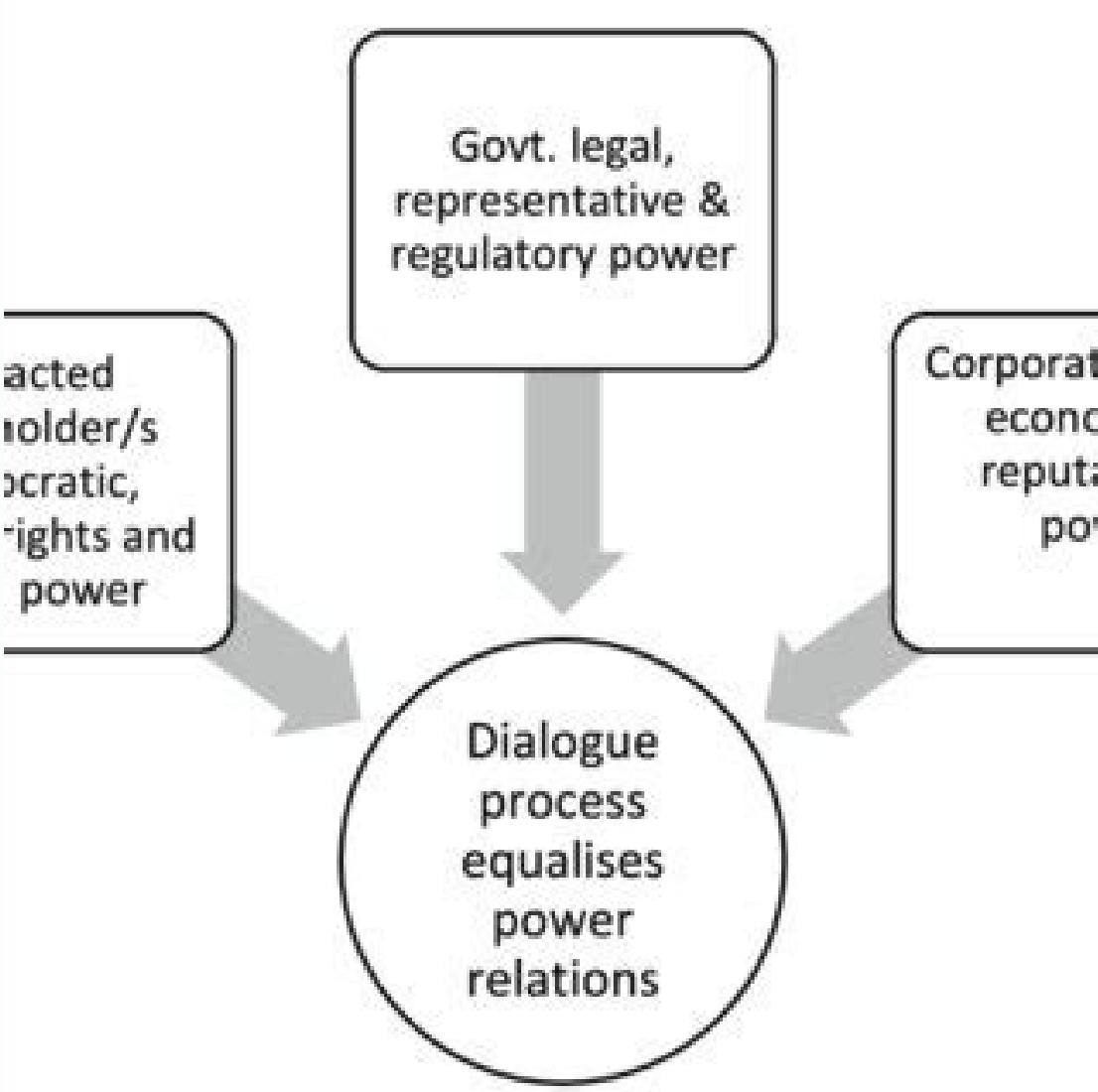
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Table 3. Data Integrity Level of Alternative Microbial Test Methods			
Microbial Test	Technology	Data Generation	Data Integrity Level
Microbial Enumeration	Automated Plate Counter	Colony Counting	High
Test for a Specified Microorganism	RT-PCR	DNA Extraction, PCR Amplification and Detection	Moderate to High
Sterility Tests	ATP Bioluminescence Respiration Flow Cytometry Solid Phase Cytometry	ATP level CO2 production and O2 Consumption Detection of fluorescent labeled cells	Moderate to High
Microbial Identification (Phenotypic)	MALDI-TOF Mass Spectrometry	Riboprotein charge-mass fingerprints	High
Microbial Viability and Antibiotic Assays	Automated Zone Readers Automated Turbidimeters	Zones of inhibition on plates Turbidity in broth culture	High
Bacterial Endotoxin Assay	Kinetic Turbidimetric Methods	Color change or turbidity due to gel clotting	High



Debadip Bandyopadhyay
Contextual Environment Questions Alcoa's Core Values Case Study

1.How would you classify Alcoa's ethical work climate? Which ethical criterion, as shown in Figure 5.1 did the company use: egoism, benevolence, or principles? Or, using Professor Paine's two distinct ethics approaches, as discussed in this chapter, was Alcoa's approach more compliance or integrity?

Alcoa (Aluminum Company of America) has a very strong values based culture and ethical work climate that wants their employees to live by the values that encompass integrity, environment, health and safety, customer, accountability, excellence, people, and profitability (Lawrence & Weber, 2011). In this case their main concern in their ethical work climate is the health and safety of its employees. The ethical criterion that seems to be most apparent in this case is that of "Principle" know as the integrity approach. It also seems from the case that benevolence (concern for others approach) could also fit the mold, but principle seems more relative.

2. What role did top management commitment play in developing the ethical work climate and organizational performance seen at Alcoa? What other ethical safeguards are mentioned in the case to support the company's efforts at developing a strong ethical culture?

Top management in the Alcoa, CEO Paul O' Neill, played an excellent and critical role in the development and implementation of the ethical work climate and organizational performance in the company. O' Neill made it imperative to identify the importance of health and safety within the company's practice. "The emphasis on safety had deep meaning to Alcoa's management team. The company's management firmly believed that no employees should be forced to work in an environment where their safety and the safety of other employees might be jeopardized. Alcoa's management supported the ethical principle that no employees should leave work in a worse condition than when they arrived" (Lawrence & Weber, 2011). Alcoa showed they cared about being compliant with the U.S. Federal Sentencing Guidelines and the Sarbanes-Oxley Act and would never jeopardize employee safety for anything, not even money. This was relevant in the case when O' Neill decided to terminate a manager who had continuous increased sales and profitability and exceptional customer and quality satisfaction reviews

3. Was O'Neill justified in terminating the manager for his lack of reporting the workplace accidents, even though no serious harm resulted from the workplace accident?

Yes most definitely O'Neil was justified in terminating the facility manager for his lack of reporting workplace accidents, incident clarification, and record keeping of occupational illnesses. Although the manager had a stellar record of increased sales and profitability and high marks in customer satisfaction, also compliant with all appropriate laws and regulations he misunderstood the company's core values. According to O'Neil, "It is equally imperative that we all learn from this and full compliance with both the letter and spirit of our policies is imperative. Anything less is acceptance."

4. Can Alcoa's "values in practice" be adopted by other organizations as a universal set of ethical standards leading to ethical employee behavior?

Alcoa principles contemporaneous. Alcoa principles pdf. Alcoa principles gcp. Alcoa principles of data integrity. Alcoa principles fda. Alcoa principles examples. Alcoa principles ppt. Alcoa principles pdf in hindi.

Assignment All data generated or collected should be allocated to person who generates the data. Original data, sometimes referred to as source data or primary data, is the medium in which the data point is first recorded. This data is then transferred to the approved protocol or form. For example: GDP will always promote the use of indel ink when completing records. Timestamps must flow in order of execution in order for the data to be credible. ¶ Questions Finally, here are some common examples where ALCOA is not used resulting in document and data integrity issues: It is very common to see the data quickly being annotated on a sticky note or on a notebook during testing. Editing should not be performed without documenting and annotating the amendments. Data should never be retroactively dated. It is important to understand where your original data will be generated so that your content and meaning are preserved. For example: if a validation protocol is run, the tests must be run and their results recorded as they are in the approved protocol. This ensures that the registration is still valid. It does so, whether it is a "result or a validation exercise, which means that the data are no longer original, present in detail and potentially inaccurate. Data integrity, quality measurement, continuous product quality review and other hot industry " will be discussed in detail in this year's Valid'run and GMP Fan. Other posts and presentations ¶ Data Integrity You can read more about Data Integrity in a presentation that our expert Trevor Schoerie did at a PDA dinner about Success by Design. Monitor your paper records/forms and format them so that there is ample room for the information to be recorded. The adjustment of an adjustment point Process or monitoring system must be done by an authorized user and the details of the change must be recorded on an audit lane. This includes the of human leg metadata which may be recorded to support an electronic record. This can be an approved database, protocol or form, or a dedicated ¶ block. All recorded data must be leg-level and permanent. Ensuring that records are legible and permanent helps with accessibility throughout the data lifecycle. Place controls/checking on manual data entry, for example, sÅ² temperature results can be entered within a predefined range from 0 to 100ÅÅ°C. Embed ¶precision checks in the design of the electronic system. For example: During a validation exercise, the test results shall be initialed and dated by the person who performs the test. For example: Use a witness check for the collection of color records to confirm the accuracy of the data. ALCOA is concerned with data, whether on paper or electronically, and is defined by the US FDA guidance as Attributable, Legible, Contemporary, Original and Accurate. Note: It is important to ensure that a register of signatures is kept in order to identify the signatures, initials and/or pseudonyms of the persons completing the paper records. When running information It is not common to see the old data scribbled, overwritten or removed using the running fluid and sometimes without an initial and date of who ran the run. Recorded data or tests performed electronically shall have a timestamp attached to the record. Writing results to a ¶ annotation block for later transcription may introduce errors. Consider how to capture data electronically and verify its accuracy. For example: Ensure that the validation test results are logged in the approved protocol. Ensure that the " of electronic systems recording data are synchronized. Consider using a master clock that synchronizes with the IT network so that the wall clocks in labors and processing machines are synchronized. 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