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VISIT TO INDUSTRIAL BIO-TEST LABORATORIES, DECATUR, ILLINOIS

On June 7, 1973, Ken Johnson (MCA), Howard Kuznetz (Shell), and myself, visited the Decatur Research Laboratories of Industrial Bio-Test Laboratories, Inc. The purpose of the visit was to observe the equipment and facilities and to discuss the program to be sponsored by MCA. We were accompanied in our visit by Ken Schadeberg, John Goode and Moreno Keplinger of Industrial Bio-Test.

Following a brief introduction, we were shown the inhalation facilities in a large room on the lowest floor of a relatively new building in Decatur. We had expected the exposure to be underway, but to our disappointment found out that, although many of the animals were on hand, the experiments were not ready to begin. We were assured exposures would be underway in 10-14 days, but after viewing the incompleted facilities, we expressed concern for this possibility. One month appeared more reasonable before exposure could start. As described, the inhalation facility is new and this will be the maiden voyage for much of the equipment. Therefore, we had many questions about the adequacy of the equipment and whether it will be shaken down before the experiment gets underway. A number of comments were made, including the following:

- 1) Because of the shape of the chambers, the large number of animals per chamber, and the fact that the cages were attached to the walls and separated by trays, there was possibility of channeling of air through the chamber. It was suggested that

an air distribution plenum, and/or a circulating fan, and certainly a plenum vent system be considered to assure distribution of air throughout the chamber. It was pointed out that it would be necessary to verify the adequacy of the air distribution by a suitable analytical method.

There were floor drains in the bottom of each chamber and there was concern that these drains' holes might become unplugged and that contaminated air could back up into the chambers from a common floor drain. It was suggested that a more positive seal such as a screw cap be considered. It was also suggested that draft gauges with alarms be included to assure closure of the chambers and operation of the pumps so that the animals do not die of asphyxia.

Because it was considered necessary to do very frequent sampling during the first part of the experiment and routine monitoring later (twice/day per chamber), it was recommended that a multi-point continuous analyzer be considered in order to reduce the cost. This analyzer could also be used to verify the distribution of air throughout the chambers. An electron capture detector on a gas chromatograph was suggested.

The orifice meters used to control the air flow into the chambers were connected by rather long, flexible hoses. It was suggested that these be shortened to decrease the likelihood of leaks. Air was supplied through a common duct, which had its inlet inside the room. It was therefore considered possible that during wash-down procedures there could be feedback into other chambers and that cross contamination should be carefully guarded against.

The matter of daily records was discussed. It was recommended that a daily log of meter readings, exposure times, flow meter readings be kept, and that calibrations of equipment become part of the experimental record. In this regard, if flow meters (rotometers) are used, they should be glass and not plastic.

There appeared to be unusually small hoses from the chambers to the common exhaust. These were obviously connected in a temporary manner with tape, but it was assumed that this was merely to check out the operation of the chambers and that they would have more permanent attachments. Exhaust from all chambers went into a common duct, which was recognized as another possible source of cross contamination.

Because of the possibility of injury and death of the experimental animals or explosion if the concentration increased to the flammable range due to failure of an air pump, it was suggested that an alarm system be included in the setup to assure movement of air through the chambers.

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In regard to records, it was pointed out that it would be necessary to account for the fate of every animal and that they should be coded in such a way as to prevent mix-ups, which could occur in the somewhat crowded conditions.

Pathological examination will be done by technicians who will make gross observations, photograph any unusual growths, and save tissues from all animals, including abnormal growths. It was stressed that all abnormal growths must be examined microscopically since this is the ultimate purpose of the study.

Everything appeared to be in order on shipment and delivery of samples and there was understanding what would be done to assure a supply on hand at all times.

One major concern was the possible number of company contacts who might approach Industrial Bio-Test for information. It was felt undesirable to allow 20 companies to be asking for information. It was determined that no information would be given by Bio-Test to anyone except Ken Johnson unless Bio-Test was specifically authorized to do so by Ken Johnson. This was considered necessary so that well-intentioned but unauthorized people from the various supporting companies would not be putting Industrial Bio-Test in the embarrassing situation of having to refuse to give information to their clients.

In summary, we are seriously concerned about the newness of the equipment and the fact that it has not been demonstrated in previous experiments to provide good air distribution. We are seriously concerned about the possibility of cross-contamination between chambers because of common inlets, outlets, and floor drains. We are concerned about the adequacy of the analysis and about the keeping of records.

Because of the excellent reputation of Industrial Bio-Test, we feel they will correct many of these problems, but it is our recommendation that the committee work very closely with them so that the experimental results are not jeopardized by technical errors. Bio-Test's personnel were impressed with the importance of the situation, and we think we have their complete understanding.

Sincerely yours,



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