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REPUBLIC OF KOREA

Technical report: Data Processing & Documentation*

Prepared for the Government of the Republic of Korea by the United Nations Industrial Development Organization, acting as executing agency for the United Nations Development Programme

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A. Introduction

This report covers the assignment of Gerald Harshman as a UNIDO consultant to KRICT during the period of January 18, 1988 thru February 5, 1988. The actual time spent at KRICT facilities was January 20, 1988 thru January 29, 1988; the remainder was briefing & de-briefing in Seoul, travel, and writing my final report.

The main purpose of my assignment was to install and instruct KRICT personnel in the use of the following systems designed to computerize many of the phases of running animal safety studies:

- 1. Body Weights/Food Consumption/Daily Observations
- 2. Organ Weights/Necropsy Records
- 3. Clinical Chemistry
- 4. Hematology
- 5. Histopathology

All of the above system are sold under the tradename of LABCAT and were designed by Innovative Programming Associates (IPA) of Princeton, New Jersey. IPA is the largest seller of computerized programs for animal safety studies in the United States and I am Director of Software Design and Development for IPA.

B. Summary

During my stay at KRICT, I successfully installed all of the above - mentioned systems and instructed KRICT personnel in their use. Working under the direction of Dr. Jung-Koo Roh, Director of the Toxicology Center at KRICT, I worked closely with the following individuals:

Mr. Lee: Acted as interpreter and sat in on all training sessions.

Miss Suh: Primary computer specialist, she was trained on all systems and will in turn train others.

Dr. Ha: Pathologist, was trained on the Histopathology system.

When I left, all systems were operational (with the exceptions noted in the detailed sections below), and at least one person nad been trained in the running of each system. KRICT is now in a position whereby they are capable of fully running each of the aforementioned LABCAT systems without outside help.

C. Software

Each of the LABCAT systems installed at KRICT is listed below along with their status as of January 29, 1988.

1. Body Weights/Food Consumption/Daily Observations

This module is the main data collection system for the in-life phase of studies up to two years in length. Normal system configuration consists of two microcomputers—a hard—disk based machine utilized for study creation, data storage, and data evaluation plus a floppy—disk based machine utilized for data collection in the animal room. Both phases of operation were demonstrated successfully and personnel instructed in their use. Two open problems exist at this time:

- (a) Additions cannot be made to the detailed dictionary at the master station--only at the remote station. This is an error which has since been corrected and will be included in the next update sent to KRICT.
- (b) KRICT requires a version of the program allowing for the housing of multiple animals within a cage. The version which includes this feature is presently undergoing testing at IPA and will be shipped to KPICT on or about March 15, 1988.

2. Organ Weights/Necropsy Records

This module is utilized during a necropsy for collecting and analyzing weight data as well as gross observations. These gross observations can then be downloaded, if desired, to the Histopathology module. The normal configuration is a hard-disk based microcomputer for study creation, data storage, and data evaluation plus a floppy-based microcomputer for data collection in the necropsy room. After KRICT personnel had been trained in the use of this system, it was utilized to collect data for a full-scale, two day necropsy involving approximately 96 animals. Only one problem was encountered during the necropsy as detailed below. This is the only problem known to exist in the Organ Weights module at this time. When entering data for many animals successively and entering weights throught the use of a function key (P1), there is a chance that the internal stack could be corrupted and an "out of memory" error would result. The logic for this section has been corrected and the fix will be included in the next update sent to KRICT.

3. Clinical Chemistry

The Clinical Chemistry module collects and reports data generated by laboratory clinical analyzers. This module runs exclusively on a hard-disk based microcomputer with interface to the analyzer taking place through the serial port. During my stay at KRICT, all internal functions of this program were successfully demonstrated as well as the valid transfer of data from the analyzer to the computer. One function remains to be tested, namely the storage of the data in the correct format at the computer end. This depends on having the exact tests run by the analyzer stored in the computer. This was not known prior to my visit, but is now incorporated into the logic based on information brought back with me. The next update of this module sent to KRICT will include this information and make the Clinical Chemistry system completely functional.

4. Hematology

The Hematology module collects and reports on data relating to blood analysis. Automatic input from an analyzer is included plus the accommodation of morphology and differential data. Like the Clinical Chemistry module, this module runs exclusively on a hard-disk based microcomputer utilizing the serial port for the analyzer interface. KRICT personnel were fully trained in all aspects of this module's operation and valid transfer and storage of analyzer data was successfully demonstrated. As of January 29, this module was fully operational.

5. Histopathology

This module offers pathologists the ability to record and analyze data relating to microscopic observations as well as to establish correlations with gross observations. The Histopathology module is completely self-contained and runs exclusively on a hard-disk based microcomputer. During my stay at KRICT, several of their personnel were trained in the use of this system, including Dr. Ha, their pathologist. No problems were encountered in running this module, and as of January 29, it was considered fully operational.

D. Hardware

Note: As a point of information, each software system comes with one (1) "system-enable" key which is required to be plugged into the hardware in order to operate the software.

As of January 29, 1988, KRICT had purchased the following hardware configurations, under my recommendation, for the running of the listed LABCAT systems:

- Two (2) AT-type microcomputers with hard-disk and one built-in high density disk drive: Histopathology system and Clinical Chemistry system.
- 2. Three (3) XT-type microcomputers with hard disk and two built-in double-density disk drives: Master Station for Organ Weights system; Master Station for Body Weights system; Hematology system.
- 3. Four (4) PC-type microcomputers with two built-in double-density disk drives: Remote stations for either the Body Weights or Organ Weights systems.

These hardware configurations are sufficient to meet present needs. Each system has a dedicated microcomputer so that no sharing of hardware is required. It follows that no switching of "system-enable" keys is necessary. This is the most efficient mode of operation and that which was recommended to KRICT.

For future expansion related to Body Weights and Organ Weights, one additional "system-enable" key has been furnished to KRICT for each of these systems. Purchase of an additional XT-type microcomputer to be utilized as a master station for each system is all that is required to create a dual operating system at a different location.

E. Recommendations

As a result of observations made at KRICT during the period in which installation of equipment and training of personnel took place, there are a number of recommendations which I would like to make which should improve performance. In general, I found the staff there very agreeable to verbal suggestions made by me--some of which were incorporated during my visit. These included: putting locks on the wheels of computer carts associated with hard-disk systems; adding electrical outlets to all computer carts; and purchasing additional hardware so that there would be no sharing of hardware between systems. The following recommendations apply to the systems and facilities as of the time that I left KRICT. Since I discussed many of them verbally with Dr. Roh and his staff, some may already have been incorporated as of this date. This list is not meant to be all-inclusive, but only a few ideas which immediately came to mind during my stay at KRICT.

1. Diskette Maintenance

- (a) At present, master copies of programs are stored in plastic boxes on the top of desks where they are not only accessible to others, but where they are subject to possible damage. A fire-proof safe area should be set up for storage of diskette master copies as well as for archival storage of data disks.
- (b) There should exist a formal procedure for periodic backup of all disks including backup of hard-disk data to either floppy disks or some other magnetic media.

2. Procedures

Written procedures should exist for the following, as a minimum:

- (a) Care of hardware
- (b) Care of software
- (c) Archival storage of data
- (d) Reporting of errors to IPA
- (e) Communication of information to IPA

3. Personnel

More people should be trained in the operation of each system. At present, some systems are known only by one individual. In order to minimize the effects of turnover, sickness, etc., as many individuals as feasible should now be trained in the operation of each system.

4. Hardware Expansion & Updating

In order to expand the capabilities of data collection for both the Body Weights and Organ Weights modules, KRICT should be ready to purchase additional hard-disk based microcomputers when facilities become available. The purchase of two additional machines would double the present capacity. Extra keys were supplied to KRICT for this purpose and no additional software is required since the present programs are 100 percent copyable. In the area of hardware updating and completing the existing configurations, KRICT should consider purchase of the following hardware items:

(a) Internal clock cards should be added to the master and remote stations for both the Body Weights and Organ Weights modules.

- (b) In case hardware sharing becomes a necessity, A/B type parallel data switches should be added so that manual swapping of keys is not necessary.
- (c) Gradual replacement of the current 5 1/4 inch disk drives with the more current state-of-the-art 3 1/2 inch disk drives should be considered. This is especially true for systems operating in the animal rooms and necropsy areas. Not only can this size diskette store twice as much information, but they are less subject to the effects of hostile environments.

5. Uploading Data to External Computers

During my stay at KRICT, the question was raised as to the desirability of uploading all data collected to an external computer for more efficient storage. Although this is certainly feasible, I really cannot recommend this procedure. In my opinion, for data backup only, the floppy disks are just as reliable and far easier to use for this purpose than an external computer. Uploading to an external computer would make sense, however, if the purpose were to use its statistical capabilities to analyze the collected data in ways not built into the module in question.

F. Conclusions

As of January 29, 1988, the five (5) computerized programs listed in Section A had been installed and were for the most part operational at KRICT facilities. This now puts KRICT on a technical level equal to the many companies in this field within the United States which have similar software. If utilized correctly, this software should greatly increase the capacity and improve the reliability of data collection for all phases of animal safety studies. In addition, data evaluation is significantly improved through the use of the computer for instantaneous generation of applicable reports.

I have included recommendations which should be given serious consideration. In addition, well-defined communication should be continued between KRICT and IPA not only for the purpose of keeping the software current, but to discuss new types of modules as they become available. KRICT is now on the leading edge of technology in the field of animal safety study automation and should now be able to serve as an example for others within this area throughout Korea.