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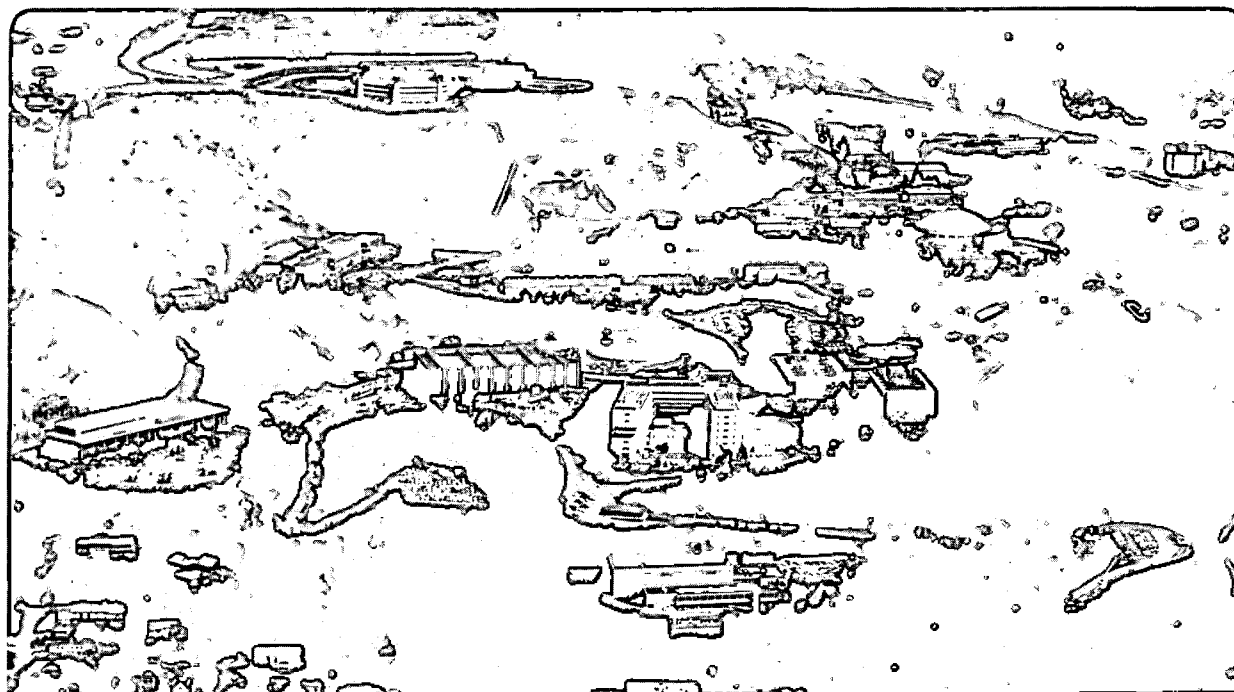## UNIVERSITY OF CALIFORNIA

Engineering Division

**Software Quality Assurance and
Software Safety in the Biomed
Control System**

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DISCLAIMER

Software Quality Assurance

and

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in the

Biomed Control System

by

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1 INTRODUCTION

The Biomed Control System is a hardware/software system used for the delivery, measurement and monitoring of heavy-ion beams in the patient treatment and biology experiment rooms in the Bevalac at the Lawrence Berkeley Laboratory (LBL). This section will describe some aspects of this system, to which reference is made later in this paper.

When the accelerator control system is instructed (by appropriate commands) to deliver beam to a patient treatment or biology experiment room, it delivers beam via a beam-line to the appropriate room. Beam is prevented from entering the room by means of a beam plug. A beam plug is a block of lead of sufficient thickness to prevent primary beam from entering the room. Only when the patient or other target is in the correct position does the Biomed operator enter the appropriate commands to cause the Biomed Control System software to pull the beam plug out of the path of the beam, and allow entry of the beam into the room. From this point till the beam plug is inserted into the path of the beam, the Biomed Control System software keeps track of all the radiation delivered to the target.

As the beam plug is pulled out of or inserted into the path of the beam, the magnets used to extract the beam from the accelerator are first turned off (clamped). This allows a fast termination of the beam and prevents the beam from scraping the

beam plug and spewing beam around the treatment or experiment room. When the signal to clamp the beam is asserted, it takes less than 1 msec to stop delivery of beam into the treatment or experimental room.

A single CAMAC branch of seven crates is used to interface all the hardware comprising the Biomed Control System hardware. One of the CAMAC modules in the system is the Biomed timing and alarm module. This module was designed and fabricated at LBL. It receives the beam-on signal from the accelerator control system. The beam-on signal is asserted by the accelerator control system just prior to each beam spill. The beam-off signal is generated by the Biomed timing and alarm module 1.6 sec later. Each of these signals results in an interrupt to the Biomed Control System software. A second function of this module is a watchdog function: a timer is started by the assertion of either the beam-on or the beam-off signal. If the module is not acknowledged by the software within 350 msec it asserts a hardware signal that clamps the extraction magnets and inserts the beam plug into the path of the beam.

2 HISTORICAL BACKGROUND

The initial version of the Biomed Control System software was developed on a PDP-11/45 computer running the RSX-11/M operating system during 1978-79. The PDP-11/45 was replaced with a PDP-11/44 running the RSX-11/MPLUS operating system during 1982-83. Finally, the PDP-11/44 was replaced with a

VAX-11/780 running the VMS operating system during 1986-87.

The software effort level for the Biomed Control System was three full-time persons during the initial design and implementation phase that lasted about a year. After that it was one full-time person and one half-time person, except for two periods of about a year each, during which it was one half-time person.

3 PHILOSOPHY

The philosophy guiding the approach to Software Quality Assurance (SQA) in the Biomed Control System has evolved over the years. In its present form, it is a distillation of the ideas in references [1] through [9]. A cornerstone of this philosophy is the firm belief that "all proposed SQA procedures and practices should be considered as guidelines and do not supercede or remove the" Biomed Control System personnel's "responsibility for the ultimate quality of the software" [5]. (This aspect of our approach to SQA existed long before reference [5].)

4 CONFIGURATION MANAGEMENT

Since the earliest versions of the Biomed Control System software, configuration management was done by means of a set of command files to re-compile and re-link all the components comprising the Biomed Control System software. The total number of modules comprising the Biomed Control System software

is about twelve hundred. Even for the earliest versions of the Biomed Control System software, this number was around five hundred. The Biomed Control System software's configuration management method was developed before the existence of today's powerful configuration management tools, and continues to be adequate for the job.

5 HARDWARE FEATURES THAT FACILITATE SOFTWARE TESTING

A hardware feature that has greatly facilitated the testing of software over the years is the CAMAC branch highway switch chassis. This chassis was designed and fabricated at LBL. It switches an entire CAMAC branch between two branch drivers, depending on the position of a single switch. One of these two branch drivers is connected to the development VAX-11/780 computer, BCSDEV, and the other to the production VAX-11/780 computer, BCSVAX. BCSDEV is used for software development; BCSVAX is used for carrying out irradiations. Thus, the CAMAC branch highway switch chassis makes it possible to switch the entire Biomed Control System hardware between the development and production computers.

Even more valuable for the testing of software is the hardware simulation that is an integral part of the Biomed Control System. One hardware simulation feature is the injection of current into all dosimeters. This is done only between the beam-on and beam-off signals, and only while the simulated beam plug is out and the real beam plug is in, and looks like beam

to the Biomed Control System. A hardware interlock is used to protect against mixing simulated with real beam: simulation is disabled if the beam transport magnets are on. (It is not possible to deliver beam to any part of the Biomed facility without turning on these magnets.) Another hardware simulation feature is the accelerator disconnect chassis. This chassis provides the simulation of timing, beam plug and magnet clamp signals. It allows the testing of the Biomed Control System without tying up the accelerator control system.

6 SOFTWARE TESTING PROCEDURES

All software development work is carried out on the development VAX-11/780 computer, BCSDEV. This computer is not normally used for carrying out irradiations, which are done using the production VAX-11/780 computer, BCSVAX. Unit level testing of all software changes / enhancements is done on BCSDEV, using the hardware features described in the previous section. Once unit level testing is complete, a software certification procedure is carried out. This procedure, like all the unit level testing, does not require the use of beam time. It uses all the hardware features described in the previous section. It consists of carrying out, for each treatment room, the calibration and patient treatment procedures. The calibration procedure uses a calibrated ionization chamber to measure the number of counts accumulated on various dosimeters that remain in the path of the beam during a patient treatment per unit of radiation as measured by the calibrated ionization chamber.

(The place occupied by the center of the calibrated ionization chamber during the calibration procedure is occupied by the isocenter of the tumor volume during a patient treatment.) The patient treatment procedure then uses this data to deliver the requested dose to the tumor volume using the dosimeters remaining in the path of the beam. These procedures are described in detail in the Biomed Control System design document. During all these procedures, a terminal screen that is updated after each beam pulse is checked. After each procedure, any output file produced by the procedure is checked. A hard-copy of output produced by the calibration and treatment procedures is saved for future reference. All output produced by the calibration and patient treatment procedures is compared for consistency with the corresponding output produced at the time of the previous release of the Biomed Control System software. Not only are changes checked, but also the parts that should not have changed.

7 RELEASE OF NEW VERSION OF SOFTWARE

When all the testing described in the previous section has been successfully completed, the Biomed Control System software is ready to be released for the next phase of testing on the production computer, BCSVAX. At this point, the system disk on BCSVAX is backed up to both tape and a removable disk pack. Then a command file is run on BCSVAX to delete the sources comprising the Biomed Control System software from the system disk, and to copy the sources from BCSDEV to BCSVAX. Once this

has been done successfully, the command file to re-compile and re-link the entire Biomed Control System software is run on BCSVAX. Next, the software certification procedure done on BCSDEV after unit level testing is repeated on BCSVAX. After this, the system disk on BCSVAX is again backed up to both tape and a removable disk pack. Finally, an entry is made in the Biomed Control System logbook stating that a new release of the software now exists on BCSVAX.

8 FINAL QUALITY ASSURANCE STEP

All the software testing described so far is done without using any beam time. Moreover, it is done by computer scientists. Before patients are treated using the newly released software on BCSVAX, one final quality assurance step is done for each treatment room. This step uses real beam instead of the hardware simulation features described in an earlier section. After daily dosimetry for the treatment room has been completed by the Biomed operator, the physicist-in-charge of the treatment room delivers radiation into a target simulating a patient in the treatment position. During this procedure, the calibrated ionization chamber is placed at the isocenter of the tumor volume. At the end of the procedure, the dose delivered to the tumor volume as derived from the various dosimeters used during a patient treatment is compared with the delivered dose as measured by the calibrated ionization chamber. The output produced by this treatment is compared with the output produced by the same treatment done under the previous version of the

Biomed Control System software. The hard-copy produced by this treatment is saved for future reference. A detailed description of the certification procedure carried out by the physicist is beyond the scope of this paper. If the outcome of this certification procedure is positive, the physicist makes an entry in the Biomed Control System logbook. Only after this has been done does the Biomed operator do any treatments in that treatment room using the newly released software.

9 SAFETY FEATURES IMPLEMENTED IN SOFTWARE

There are several hardware and software features in the Biomed Control System to ensure the safety of patients treated in the medical treatment rooms in the Bevalac. These safety features are described in the following sub-sections. This section does not describe those safety features that are implemented in hardware alone.

9.1 Acknowledgement Of The Watchdog Module

As mentioned in an earlier section, the Biomed timing and alarm module is a CAMAC module that receives the beam-on signal from the accelerator control system and generates the beam-off signal. It also contains a watchdog which is armed at each beam-on and beam-off signal. If the Biomed timing and alarm module is not acknowledged by the software within 350 msec, it asserts a signal that clamps the extraction magnets and inserts the beam plug into the path of the beam. The Biomed Control System software receives an interrupt that is generated by each

beam-on and each beam-off signal. It then reads the state of the hardware, does computations based on the data read, and finally acknowledges the watchdog module. Thus, the watchdog module protects the patient or experimental target not only in the event of a computer crash in the middle of an irradiation, but also in the event of several crucial software components aborting or hanging.

9.2 Loading The Preset Scalers

There are multiple preset scalers dedicated to patient treatments in each treatment room. They are connected to different dosimeters, via independent hardware paths. This protects the patient in the event of failure of a single dosimeter, or a failure at a single point along the hardware path to the preset scaler. These preset scalers are loaded before the beam plug is pulled out of the path of the beam, and then re-loaded after each remaining pulse of the treatment. Note that initially the beam plug is not pulled out of the path of the beam until the preset scalers have been successfully loaded. This protects the patient in the event that the program carrying out the patient treatment aborts or hangs.

9.3 Loading The Manual Preset Scalers

There are multiple manual preset scalers dedicated to patient treatments in each treatment room. Like the preset scalers, they are connected to different dosimeters, via independent

hardware paths. Unlike the preset scalers, however, the computer has no way of loading or reading the manual preset scalers. The program that carries out patient treatments prompts the Biomed operator with values to manually load into the manual preset scalers. If the values are reasonable, the Biomed operator loads the manual preset scalers and enables them. The manual preset scalers are used as backups to all the computer-controlled cutoffs. Hence, the values loaded in them are 2% higher than the exact counts that would complete the treatment.

9.4 Operator Checks Before Pulling Beam Plug

The patient treatment procedure displays the prescription file for the treatment and waits for the Biomed operator to check with the treatment personnel that this data is correct.

The patient treatment procedure displays the beam-line setup and again waits for the Biomed operator to verify with the treatment personnel that each device is in the correct state before proceeding with the treatment.

The state of all the devices on the optical bench that are not computer controlled is checked before pulling the beam plug. Once these devices are in the correct state, they will remain in this state during the treatment.

9.5 Operator Monitoring During Treatment

The patient treatment procedure displays the expected and delivered counts on an upstream ionization chamber. Also displayed is the expected and delivered dose, the setting of all the range absorbers in the path of the beam, etc. The Biomed operator and the treatment personnel check this display during the treatment.

The position of the beam on the upstream and downstream ionization chambers is displayed after each beam pulse, and checked by the Biomed operator and treatment personnel.

9.6 Beam-on Checks

Following each beam-on signal (before each beam pulse), the patient treatment program checks that the counts delivered during the previous background (counts accumulated during beam-off cycle) on several dosimeters are less than a pre-determined number. The patient treatment program also checks the setting of any range absorbers in the path of the beam. For one of the treatment rooms, the treatment program checks that the delivered magnet current for the Wobbler agrees with the requested magnet current. (A hardware check is also made for this.) For the other treatment room, the treatment program checks that all five coordinates of the patient positioner (ISAH) agree with the desired values. (These checks are specific to each treatment room because the Wobbler exists only in one treatment room, and the ISAH patient positioner in

the other.)

If any of these checks fails, the treatment program clamps the extraction magnets, inserts the beam plug into the path of the beam, interrupts the treatment and saves all the data necessary to resume the treatment later.

In general, those devices on the optical bench that are computer controlled are checked every beam pulse.

9.7 Beam-off Checks

Following each beam-off signal (after each beam pulse), the patient treatment program checks if the delivered dose exceeds the desired dose. Checks for range absorber settings, Wobbler magnet current and ISAH coordinates are also performed, as in the beam-on checks described above.

If any of these checks fails, the treatment program clamps the extraction magnets, inserts the beam plug into the path of the beam, interrupts the treatment and saves all the data necessary to resume the treatment later.

9.8 On-line Diagnostics

The process of installing the Biomed Control System software includes starting up a diagnostic program. This diagnostic runs at a very low priority. It writes a certain bit-pattern into a CAMAC test module in each crate in the system, and reads

back the data that it wrote. If the data read back agrees with the data written, it goes on to the next crate or the next bit-pattern. If, however, the data read back does not agree with the data written, it asserts a signal to clamp the extraction magnets and insert the beam plug into the path of the beam.

9.9 Recovering From An Interrupted Treatment

If a patient treatment is interrupted by insertion of the beam plug into the path of the beam, the treatment program asks the Biomed operator what to do. After the problem that caused the interruption has been corrected, the Biomed operator can tell the treatment program to continue with the interrupted treatment. In this case, the treatment program prompts the Biomed operator with the new set of values to load into the manual preset scalers. When the Biomed operator indicates that this has been done, the treatment program pulls the beam plug and continues with the interrupted treatment.

Sometimes, however, the problem that caused the interruption is not immediately correctable. (For example, the patient is too sick to continue with the treatment, or the accelerator has a fault that will take several hours to fix.) In this case, the Biomed operator instructs the treatment program to exit. The treatment program then saves its internal state in a file in order to be able to resume the interrupted treatment at a later time. Whenever the treatment program is entered, it asks the

Biomed operator whether a previously interrupted treatment is to be resumed. If so, it looks for the file containing the data that permits it to resume a previously interrupted treatment.

Since it is possible that a computer crash could occur during a patient treatment, a snapshot of the state of the patient treatment program is written out to disk after each beam pulse. When the Biomed Control System software is installed, one of the first things done is to check this snapshot. If the snapshot indicates that a patient treatment was in progress, a file containing the state of the treatment program is created. This makes it possible to subsequently resume the interrupted treatment.

9.10 Data Logging

For each irradiation done, the Biomed Control System software keeps a comprehensive record. Included in the data logged is the setup of the optical bench (the position and identification of each device), the dose delivered to each dosimeter, the setting of all range absorbers, etc. In addition to this, the logged data also includes the total counts delivered to each dosimeter. This makes it possible to subsequently re-check the calculation of the delivered dose, if so desired.

The only program that does not maintain this extensive record

is the procedure that is used for tuning the beam. During the beam tuning procedure, the beam position, beam shape, beam stability, dose rate, etc., are observed and optimized. There is no need to keep a record of the tuning process.

In addition to all of the above, the patient treatment program produces a one or two page summary of each patient treatment carried out. The Biomed operator has the option of printing this file for inclusion in the patient's medical file.

10 ACKNOWLEDGEMENT

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