Statement by Marshall Brucer

on F.R. Document 59-3662 entitled "Atomic Energy Commission (10 CFR Part 20) Standards for Protection against Radiation" published in the Federal Register on Saturday, May 2, 1959.

In setting up the Atomic Energy Commission in Public Law 703 (83rd Congress) it was the will of Congress that certain rules be established. In general this has been accomplished with distinction as is attested to by U.S. primacy in atomic energy. The Congress through its "Joint Committee on Atomic Energy" has assisted immeasurably. The two volumes of hearings published in 1957 on fallout are now world famous as "the encyclopedia."

The Congress directed the AEC to "...permit the widest amount of effective medical therapy" and to "...impose the minimum amount of regulation." Congress imposed only one overriding restriction on the AEC and through it, by implication, on nuclear medicine. This criterion, I believe, should be the primary one of practice: "...unreasonable risk to the common defense and security and to the health and safety of the public."

However, occasionally a government bureau will go too far, too fast, and will extend its authority beyond reason. F.R. Document 59-3662 is such an extrapolation. It was published on May 2, 1959, and becomes a federal regulation on June 2. The document has teeth - enormous teeth. These have been used rapaciously in the Kellogg Company incident and are now being used, I think, against the Elgin National Watch Company. The malignity of the document will, in effect, destroy private initiative in the field of nuclear science.

Paragraph 17 states that "...based on present knowledge and experience it is believed that the levels established provide a high standard of safety..."

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This is certainly true. It would also be true if the Commission prohibited all radiation. This would be a "high standard of safety," but this should not be the aim of the Commission. The aim should be to provide the standard of safety that was determined by Congress, "...unreasonable risk to the common defense and security and to the health and safety of the public." For the Division of Licensing to set up a different standard, which is not only contrary to the trends of scientific opinion but is also contrary to the will of Congress, is in my opinion an unbelievable presumption on the part of any organization within the government.

Unfortunately, I cannot get a copy (let alone enough copies to send each of you one) but I think it is important enough to medical science for you to get one and comment on it. For ease of reference I have numbered the unnumbered paragraphs 1 through 19 and then have followed their numbering system in the document.

Trends of Opinion

Paragraph 6 states that there is no positive evidence of damage due to the use of earlier permissible dose levels. Paragraph 7 goes on to state that the purpose of the document is merely "based on the desire to bring the MPD into accord with the trends of scientific opinion."

In the first place, if there has been no damage from the old MPD levels, why is there a necessity for change? In the second place these changes are not based upon current trends in scientific opinion, but are based upon a manufactured public opinion. On page 851 (Hearings before the Joint Committee on Atomic Energy, the 85th Congress, June 1957) Dr. Taylor states that according to the best opinion (the ICRP), scientists still feel the same about lowered MPD "but were stampeded by public clamor."

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As Santayana pointed out many years ago, those who do not remember history are condemned to live it all over again. The word "condemned" is very appropriately used. This is not the first time we have gone through a period of radiation hysteria. It is actually the third time. Back in 1905 the radiation scientists of that day went through a period of professional radiation hysteria that had very good reason and laid the real background for radiation safety. It reached its peak in about 1905 and then disappeared gradually from the professional literature, partly from contempt and partly from knowledge. Lagging behind this professional hysteria, there was a period of public radiation hysteria. It reached its peak in about 1909 and then disappeared, partly from contempt and partly from knowledge. The current radiation hysteria is almost identical to this wave that occurred in 1909. I think we reached the peak of professional hysteria in about 1958. This is definitely on the wane, and the May 1959 issue of Radiology is good evidence of its waning importance. This, however, is not the only evidence. Almost every scientific journal is showing an increasing professional awareness of the fact that we have passed through a period of hysteria and that "radiation dangers" are to be minimized, not maximized as is done in the new proposed rule making. Still, the current public hysteria is going to lag behind our waning professional wave. I am predicting that its peak will not be reached until about 1960 or 1961. The proposed rule making by the Division of Licensing is not following the current trends of scientific opinion. Rather, it is more concerned with the current wave of public hysteria. The purpose of F.R. Document 59-3662 apparently is to assuage a public opinion that has been manufactured by professional pacifists, malcontents, and persons looking for increased research funds in certain fields.

The whole point of any rule making should be to pound in the fact that there is a real radiation danger in uncontrolled, unregulated, uninterpreted,

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and unknown high levels of radiation. F.R. Document 59-3662 breeds contempt: herein lies the real "...unreasonable risk..."

Dosimetry

a) Section 20.101 supposedly states the newest requirements of the NCRP. The last Addendum I have to Handbook 59 by the National Bureau of Standards is dated January 8, 1957. However, I have so many amendments that it is impossible to keep track of them. Section 20.101 does not state, according to my interpretation, the same meaning that is stated in the latest amendment of Handbook 59. For example, the NCRP recommendation was that the maximum permissible dose "to the most critical organs" shall not exceed three rems. Section 20.101 states "the dose to the whole body shall not exceed three rems." Under no conditions can these two statements be considered to be equivalent. Section 20.101 implies "and gonads." The NCRP states "or gonads." These are not the same. It is perfectly obvious that the person who wrote Section 20.101 did not understand radiation dosimetry. However, it is also perfectly obvious that the NCRP recommendations have become a numbers game that is not understood by anybody except a few persons who are using a language of their own.

b) Appendix B contains values that are calculated under a highly restricted set of assumptions. These assumptions on the methods of calculation are known to a small handful of health physicists. Many persons do not agree, either with the methods of calculation, the basic assumptions, or with the use to which these tables are put.

For example, the dose rate concentration for carbon-14 and its body burden is given in the form of an assumed soluble compound. Such carbon-14 materials as sulfasuccidine and ethyl alcohol might both be soluble carbon-14

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containing materials. However, the sulfasuccidine would be a nonabsorbable molecule, whereas ethyl alcohol goes through a very special kind of absorption. The radiation dose rates leading to body burdens or air and water hazard concentrations are entirely different. The same thing can be said of any one of the items listed in Appendix B. For many of these items the decay schemes are so little known that the table could be calculated only by the wildest possible assumptions. This whole appendix has been calculated, recalculated, amended, and changed so many times that very few experts, even within the Commission, are sure of its meaning. This table is of enormous value to scientists who are interested in the problems of radiation protection. The table furnishes a guidepost for experimental and for diagnostic use. So long as it is used only as a guidepost, it has value; but it has no place in rule making.

c) Paragraph 11 states that the values specified in Appendix B are real levels beyond which one must have specific approval from the Commission. This certainly is not the intention of the Handbooks, and since many of these values are unmeasurable even by experts, and are certainly unmeasurable by almost all of the licensees, it is hard to see how anyone could possibly use the table as proposed. I do not know of one single person in the Inspection Division of the Atomic Energy Commission that can measure the values proposed in Appendix B. If these cannot be measured by the Inspection Division, I see no way of enforcing them. If they are beyond enforcement, then there is no reason for the proposed rule making.

d) The proposed rule making states in Section 20.105 that every licensee shall guarantee that no person in an unrestricted area will get in excess of 1250 millirem per quarter. Depending upon geography this is conveniently close to a background level. No licensee can guarantee the

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level of background unless he has measured it in his particular geography. Since the Commission itself does not know the backgrounds in the areas of its own operations, it cannot expect licensees to meet these requirements. I see nothing in the proposed rule making that exempts Section 20.101 or Section 20.105 from the background radiation levels. Furthermore, background is definable only operationally, never generally; therefore, the subsections appear to be, not only ambiguously written, but subject to highly variable interpretations by different experts in different fields.

e) It appears that Section 20.106 jumps from the external radiation levels talked about in Section 20.105 to the concentrations in effluents which must indicate a concern with internal radiation. Not only are these sections subject to varying interpretations, but they specify various integration periods and demand the application of instruments which are not available, even in Commission laboratories. Under these circumstances it is highly improper to expect every licensee to be able to meet the requirements. If this statement were to take into account the spirit rather than the letter of the rule making, in order to follow Section 20.106 one would have to take into account such items as reconcentration, the lack of controls over air pollution, and the fact that subsection (c) can only be considered an abrogation of responsibilities in order to meet the demands of an operational possibility. This section cannot be met in the spirit in which it was written. It can only be met in terms of the letter of the law because of the modification in subsection (c).

f) In Paragraph 14 the Division of Licensing states that it does not require licensees to calculate "combined" exposures from both internal as well as external radiation. It states that these methods of combining exposures are not sufficiently well developed. If this statement is to be accepted at face value, then the proposed rule making is only for either

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internal or external radiation. If it is for only external radiation, then it has no value in bioassay services and there is certainly no need for Appendix B, which is concerned only with body burdens. If this document is written only for internal radiation, then Section 20.101 is unnecessary since it is written wholly around external exposure data, as is explained in the section itself. In other portions of the document the use of film badges and pocket chambers is mentioned. This, obviously, refers only to external exposure. A large number of isotopes are mentioned with permissible concentrations in water and air and only refer to internal exposures. The writing in Paragraph 14 states that

> "For a number of reasons the Commission has decided that it is not desirable at the present time to require calculation of such 'combined' exposures. Knowledge of the relative effect of exposure to internal and external radiation and means for calculating 'combined' exposures are not sufficiently well developed for this to be a workable procedure."

If the procedure is not workable for both internal and external procedures, but if both internal and external protection is mentioned in the proposed rule making, then this paragraph must be ambiguous.

g) Paragraph 8 points out that a literal application of the new NCRP recommendations to individual persons requires a determination of previous exposures and all the reasons why this cannot be done. It then suggests a wholly fictitious assumption that has neither basis in fact nor does it add anything to an understanding of a person's previous radiation history. This is purely and simply a bookkeeping procedure.

It is stated that the licensee may take "advantage of any additional exposure." However, the instructions in Section 20.101 merely indicate a

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rearrangement of spatial and temporal details. In connection with the statements concerning dosage, it should be pointed out that of all of the real radiation accidents that have occurred, in only one accident has there been a dosimetry that could even roughly be approximated. In the Y-12 accident it was possible to completely rerun the accident as an experiment and to achieve a "best possible" dosimetry. This is a highly unusual event. In every other accident the estimates are considered to have an error of many orders of magnitude. With dosimetry so highly uncertain, even in the ranges that are within the purview of our instrumentation, it is intellectually incredible that a legal paper should be based on them.

h) Section 20.3 contains a definition of occupational dose. It exempts exposure of a person for purposes of medical diagnosis and therapy; however, it does not specifically exempt the personnel who are preparing doses for medical exposure. The interpretation of the Inspection Division of the Atomic Energy Commission of this kind of wording (even <u>if</u> these levels were dangerous, which they <u>are not</u>) during the past few years has been that, although the patient himself is exempted, the physicians, technicians, chemists, and employees of a pharmaceutical house are not hereby exempted. No pharmaceutical manufacturer can prepare radioactive drugs for medical purposes under these regulations and still earn a profit. Very few licensees within the medical profession have facilities available to guarantee their meeting the requirements of this proposed amendment. The only instrument that could possibly come near measuring doses at levels required in Appendix B is a total-body counter of advanced design. The Commission in other actions is discouraging the acquisition of total-body counters by medical personnel. Therefore, the inclusion of the medical exemption can only be interpreted as a verbal gambit meant either to forestall obvious criticism or to cover some far more sinister purpose.

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i) The use of the rem in calculating exposures is a legal fiction. The rem is not a measurable unit. Therefore, there are no instruments that can be applicable. It contains the rad and the RBE in its calculation. The rad is calculated or measured on the basis of a particular absorbing material. The RBE is calculated only in terms of a particular biological system and a particular biological effect. Since the RBE has never been calculated except in terms of the grossest possible assumptions for any human system, it is obvious that the rem does not apply to human systems. Therefore, it can be stated that the rem as used in the forms demanded by the proposed rule making does not apply to humans. The original Handbook 59 states:

> "...it should be noted that because the RBE is influenced by a great many factors, strictly speaking, there is no such thing as exact equivalents of biological damage produced by X rays and other radiations of markedly different specific ionization, in a biological system in which more than one effect takes place."

Since the whole function of this proposed rule making is with the prevention of biological damage, the use of the rem as a unit of radiation measure vitiates the entire document. It should also be pointed out that the rem is not agreed to by current trends of scientific opinion. If anything, current scientific opinion considers the rem as having no place in anything except animal studies.

The Bioassay Procedures

a) Paragraph 13 states that authority is reserved to require the furnishing of bioassay services. It also explains that "routine" bioassay requirements will be incorporated in certain unstated specific licenses. A

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bioassay is not a defined item. It can range all the way from a simple urinalysis to a serial section autoradiogram of the brain. The same type of legal protection on this demand is necessary, as has been shown to be necessary in balloon tests in alcoholism and blood tests in venereal disease control. These are matters that have medical implications and should be under the ultimate control of persons who have licenses from a particular state to practice medicine in that state. It is not a matter to be discussed openly as a "routine."

b) If someone should want to sue a licensee for overexposure, he should have this privilege. The requirements of Section 20.108 state that all bioassay data must be made known to the Commission. This immediately removes all bioassays from their historical status as privileged documents and destroys one more right of the individual. In my opinion, this is an item for legislation, and not for rule making.

The Reporting of Data

a) Paragraph 15 states that licensees will be required to furnish periodic reports to employees on forms that were not printed in the Federal Register. After many days of delay, I have finally been able to obtain one copy of the document printed by AEC that includes these forms. This was borrowed, not from the Division of Licensing, but from the Oak Ridge Operations Office. I have tried to fill out these forms for myself and a number of Medical Division employees. It is perfectly obvious that none of us understood the form, nor were any of us capable of getting the data necessary. The forms must be certified by the employee, and yet the employee could not make the esoteric calculations necessary to complete the forms. Therefore, it can only be presumed that these forms are not meant for the

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protection of employees. They are designed for the convenience of one very small group of persons within the Commission.

b) Paragraph 16 states the permission necessary for the destruction or disposal of such records. In addition to the fact that we would have to hire, if we were a licensee, a whole new staff of health physicists, clerks, and typists to maintain records, we would also have to have a revision of the current regulations on the number of file cabinets we are allowed to keep. If it is necessary for the licensee to maintain an enormous file of unnecessary health physics records until five years after the termination of each individual's employment, then we might just as well stop work and do nothing but keep records.

c) The proposed rule making recognizes that it is difficult to determine the appropriate period for which records of radiation exposure should be preserved. Certainly the five-year period is nowhere near the period that most biologists recognize as the period of chronic exposure effects. In other places the Division of Licensing points out that delayed exposure effects extend even beyond the lifetime of the individual. In this proposed rule making it allows a five-year period. The two statements are incompatible.

d) Section 20.401 requires that each licensee shall maintain records on various AEC forms. It should be noted that the section states that the doses entered on the forms shall be for periods of time not exceeding one month, and yet the form itself states that the running total is to be maintained on the basis of calendar quarters. It would appear that this is an ambiguously written statement.

e) Sections 20.403 and 20.404 provide for informing persons of their accumulated dose. To give a group of persons who are not trained in

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the special field of the interpretation of the brand of dosimetry required by the Division of Licensing, a statement of dosage that cannot be understood, even by experts within the Commission, can do nothing more than further confuse an already confused picture.

f) According to Section 20.202 every licensee, and this will eventually include every medical organization, has to give personnel monitoring equipment to every person who enters the property of the licensee. Each therapeutic patient who receives a gamma-emitting isotope automatically produces a high-radiation area. This means that every person who enters the hospital must be furnished with personnel monitoring equipment. The proposed rule making also states that every visiting child must be given personnel monitoring equipment, in spite of any calculations or predictions as to levels. The only way in which medical personnel could meet this requirement is by stopping the use of radioisotopes.

The Division of Licensing is Against the Licensee

a) Paragraph 10 states that overexposures are contrary to the Commission's regulation. The essential item in this paragraph is that for overexposures the Division of Licensing intends to institute "proceedings against the licensee." There is no indication that the Division of Licensing intends to institute proceedings for the licensee. All the many alternatives to criminal litigation are foresworn by the Division of Licensing. There is no indication of an intention to assist. There is no indication of preventing further occurrences. There is no indication that the Division of Licensing has anything except a negative approach.

But this paragraph is historically accurate. The history of the Houston incident and the forcing out of business of a major industrial

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licensee is an indication that this paragraph is not without danger. The Division of Licensing states that "the proposed regulation does not adopt such an approach (to remove individuals from employment)." However, the proposed regulation does just this.

b) High-level radiation is the one place where the Commission's legal teeth should be exposed at their fullest. There is a therapy for accidents. The Commission has contractors capable of giving help. Some inspectors within the Inspection Division are capable of thinking preventively. To fall back on "institution of formal proceedings" is too little and too late. Cooperation will always be possible provided the teeth of the Commission are used for and not against the licensee.

Guides and Not Rules Are Required

a) The "Addendum to National Bureau of Standards Handbook 59, Permissible Dose from External Sources of Ionizing Radiation" dated January 8, 1957, states that the Handbooks are a "set of guides" and that "in spite of the trends, it is believed that the risk involved in delaying the activation of these (Handbook) recommendations is very small, if not negligible." Most of F.R. Document 59-3662 appears to be built around a protection factor of about ten times natural background. In this regard it should be quoted from Handbook 59 that

> "The only statement that can be made at the present time about the lifetime exposure of a person to penetrating radiation at a permissible level considerably higher than the background radiation level, but within the range of radiological experience, is that appreciable injury manifestible in the lifetime of the individual is extremely unlikely."

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Further on Handbook 59 states:

> "Lack of extensive long-term practical experience under controlled conditions precludes an a priori accurate determination of the risk for any exposure level that may be adopted. The only thing that can be done at present is to adopt the value that in the light of all available information can be confidently expected to conform with the criterion of acceptable risk."

The proposed rule making does not use a criterion of "acceptable risk," but rather uses the impractically stringent requirement of "no risk."

In the original Handbook 52 definite rules for establishing computed MPC's are stated:

> "...must be set on the assumption that the occupational exposure will continue throughout the working life of the individual and environmental exposures will continue for a lifetime.... The physical state and the chemical form of the radioisotope help determine the type of radiation hazard and to some extent the degree of retention in the body and the magnitude of hazard."

These values are based upon radiation from external sources. They are based on an assumed RBE. Their value is extrapolated to man. In some cases they are based on the assumption of soluble compounds, on the assumption of retentions in portions of the body, on assumptions of the radiosensitivity of tissue, on the assumptions of certain sizes of critical organs, on the assumptions of criticality of organs, on the assumptions of biological half times. Although all these assumptions lead to a still valuable guidepost, they are not proper subject matter for restrictive rule making.

b) At this point I may seem to rulemakers to reverse myself. I believe the Commission should establish a "safe" level of radiation and

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attempt to live within it. I even concede the use of the word "safe" because it is understood. But if the word is used, it should be at a defined level that is understandable to every licensee and to every expert. The old 300 mr level was misunderstandable only to a few experts. Therefore, it was a good level for guidance. The refined details of technical expression, without exception, can be summarized as disagreements in dosimetry. No agreement can be forced in this field, and, hence, no rule can be enforced.

Summary

If this document were to be followed seriously, it would mean the end of the use of radioisotopes in medicine. It almost certainly will restrict the use of radioisotopes to a monopoly of Commission-supported medical organizations that have unlimited funds for health physics studies. It is certainly contrary to the will of Congress, who in Public Law 703 has directed the AEC to "...permit the widest amount of effective medical therapy" and to "...impose the minimum amount of regulation."

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