

ALARA and an Integrated Approach to Radiation Protection

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Exposures of individuals to ionizing radiation have been restricted for many years by a number of guidelines and rules developed by various advisory and regulatory groups. Accompanying these restrictions has been an evolving principle that exposures to individuals and groups should be kept "as low as reasonably achievable" (ALARA), consistent with provision of the benefits of radiation use to society. Although the ALARA concept is a laudable goal in principle, its implementation in a clinical facility has not been a straightforward process. Problems of

implementing ALARA have been confounded further by the efforts of regulatory agencies to incorporate the ALARA concept into regulations governing radiation exposures. To facilitate the implementation of ALARA as a workable construct in a clinical facility, guidelines are needed for its application to both individual and collective exposures to radiation. The provision of such guidelines, including action and inaction levels for both individual and collective exposures, are presented here.

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THE FIRST officially sanctioned limit on the exposure of individuals to ionizing radiation was the "tolerance dose." This limit was defined in 1927 as 1/100 of an erythema dose per month, where an erythema dose was the amount of radiation required to produce erythema (skin-reddening).¹ In the next year, the roentgen (R) was defined as the official unit of x-ray measurement, and the International Commission on X-ray and Radium Protection (now known as the International Commission on Radiological Protection [ICRP]) was formed to quantify protection standards for radiation. In 1934, the ICRP recommended a tolerance dose of 0.2 R/d; in the same year, a similar committee (now known as the National Council on Radiation Protection and Measurements [NCRP]) in the United States announced a tolerance dose of 0.1 R/d as an upper limit to the exposure received by persons working with radiation.²

Soon after World War II, several modifications were made in the permissible exposure to ionizing radiation. The tolerance dose was reduced to 0.3 R/w and was confined to certain radiosensitive regions of the body (the whole body, blood-forming organs, gonads, and lens); other less sensitive regions (eg, the extremities and skin) were permitted higher exposures.³ In addition, the varying effectiveness of different radiations to produce biological damage was

expressed in the definition of relative biological effectiveness (RBE).

By 1958, the concept of tolerance dose was no longer considered appropriate and was replaced by the term "maximum permissible dose." This change was made to emphasize the assumption that biological organisms, including humans, have no innate tolerance for radiation; any exposure, no matter how small, increases the risk of biological damage, with the degree of risk increasing with the exposure. By this date, the "rem" was well established as a radiation unit that encompassed both the radiation-induced deposition of energy in tissue and the effectiveness of the deposition in inducing biological damage. The maximum permissible dose* was defined as 5 rem/y for occupationally exposed individuals and one tenth of that amount (0.5 rem/yr) for members of the general public. Maximum permissible doses also were defined at higher levels for selected organs and anatomical regions, and provisions were made for slight overexposures in any given year, provided that the cumulative dose over an extended period remained below an average value of 5 rem/yr.

Over the years, recommended exposure limits for ionizing radiation have shown a downward trend. There are two reasons for this trend. First, knowledge of the types and magnitudes of the

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*Today, expressions to quantify radiation have explicit definitions and units. Exposure describes the ionization produced by radiation in air and is measured in roentgens. Absorbed dose describes the energy absorbed in irradiated matter and is measured in rads. Dose equivalent is the absorbed dose adjusted for its biological effectiveness and is measured in rems. In the remainder of this discussion, the term "dose" is understood to imply dose equivalent.

biological effects of radiation has increased over the years. Second, technologic advances have permitted an expanding use of radiation in medicine and in other societal applications with a decreasing dose of radiation to workers and to the public. For many years, it has been assumed that there is no "safe" dose of radiation, no matter how small; on the other hand, it also is recognized that there are doses so small that reductions of personnel exposure below these levels would be exorbitantly expensive and would provide no recognizable reduction in biological risk. In summary, the setting of limits for the exposure of individuals and groups to radiation requires judgment of the balance among radiation risks, the costs of radiation protection, and the benefits derived from uses of radiation in society. The exercise of this judgment is embodied in the concept of ALARA defined officially by the ICRP in 1977.

A chronology of major events in the history of radiation protection agencies and standards is provided in Table 1.

THE CONCEPT OF ALARA

The concept that exposures to individuals and groups should be kept "as low as practicable" (ALAP) or "as low as reasonably achievable" (ALARA) has been an operating principle for many years of agencies responsible for develop-

ing and enforcing standards for radiation protection in this country and elsewhere.⁴ The concept was born during the Manhattan Project of World War II and was acknowledged by the NCRP in 1954 in the statement that radiation exposure should "... be kept at the lowest practical level."⁵ The ICRP made a similar recommendation in 1959.⁶ These agencies, together with other advisory groups on radiation protection, have continued to endorse the concept of ALARA, although with some modifications in definition and terminology over the years. Recently, for example, the ICRP adopted the expression "optimization of radiation protection" (ORP) in place of ALARA to avoid confusion caused by utilization of ALARA as an enforceable process by certain regulatory agencies.

The present conceptual framework of ALARA was described by the ICRP in 1977⁷ as a philosophy of radiation protection based upon quantifiable risk. The ICRP stated:

"Most decisions about human activities are based on an implicit form of balancing of costs and benefits leading to the conclusion that the conduct of a chosen practice is 'worthwhile.' Less generally, it is also recognized that the conduct of the chosen practice should be adjusted to maximize the benefit to the individual or to society. In radiation protection, it is becoming possible to formalize these broad decision-making procedures though not always to quantify them. . ."

Table 1. Chronology of Major Events in the History of Radiation Protection Agencies and Standards

1895	X-rays are discovered by Wilhelm Roentgen.
1896	Various reports of adverse health effects of x-rays begin surfacing. E. Thomson purposely exposes a finger to a large dose of x-rays.
1902	Death of one of Thomas Edison's assistants is related to x-ray exposure.
1913	German Roentgen Ray Society makes the first formal safety recommendations.
1915	British Roentgen Society suggests safety standards.
1920	Deaths from exposure to radium are reported. French Academy of Sciences Study Commission is formed.
1925	Tolerance dose is estimated independently by several researchers: 1/100 erythema dose per month. First International Congress of Radiology is formed. International Commission on Radiation Units and Measurements is formed.
1928	Second International Congress of Radiology officially adopts the roentgen as a unit of radiation. International Committee on X-ray and Radium Protection (ICRP) is formed. Advisory Committee on X-ray and Radium Protection (ACXRP) is formed.
1934	ACXRP recommends tolerance dose of 0.1 R/d. ICRP recommends 0.2 R/d.
1941	National Bureau of Standards Advisory Committee recommends a maximum residual body burden of 0.1 μ g radium.
1942-1945	Manhattan Project is started as a crash program to develop the A-bomb.
1949	NCRP recommends maximum permissible dose (MPD) of 0.3 R/wk.
1950	ICRP recommends MPD of 0.3 R/wk.
1958	NCRP recommends MPD of 5 rem/yr occupational and 0.5 rem/yr for the general public.
1959	Federal Radiation Council (FRC) is formed; recommends MPD of 0.17 rem/yr average exposure for the general public.
1970	FRC is dissolved. Environmental Protection Agency is formed.
1977	ICRP: As Low as Reasonably Achievable (the ALARA principle).

The ICRP recommended a system of dose limitation, the main features of which are: (1) no practice shall be adopted unless its introduction produces a positive net benefit; (2) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; and (3) the dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission. That is, the approach of the ICRP was to cast radiation protection as decision analysis, with the decision criteria couched in terms of net benefit and economic and societal cost.

DOSE-EFFECT MODELS

As a philosophic construct, the concept of ALARA is a straightforward process: radiation exposures should be kept as low as possible, consistent with the realization of benefits of radiation use to society and with common sense with regard to cost and convenience. The difficulty arises when the construct is applied to real exposure conditions. To appreciate this difficulty, it is necessary to consider different dose-effect models for biological risk resulting from radiation exposure.

Although radiation effects have been studied for many years, significant uncertainties remain concerning the exact relationship between radiation exposure and biological effects. These uncertainties are especially pronounced at the low levels of exposure encountered in the work environment. The uncertainties occur principally because the magnitude of the effects is small and because the nature of the effects (cancer induction [carcinogenesis], developmental abnormalities [teratogenesis], and genetic effects [mutagenesis]) is identical to those that occur spontaneously in humans not exposed to radiation other than background. To address the uncertainties, various dose-effect models have been postulated that accommodate the best available bioeffects data and that are considered "conservative" because any error tends to overestimate the risk in the opinion of proponents of the model. Three dose-effect models have received the greatest attention recently: the linear-quadratic model, the linear model, and the supralinear model. These models are depicted in Fig 1 and are discussed in detail in the 1980 report of

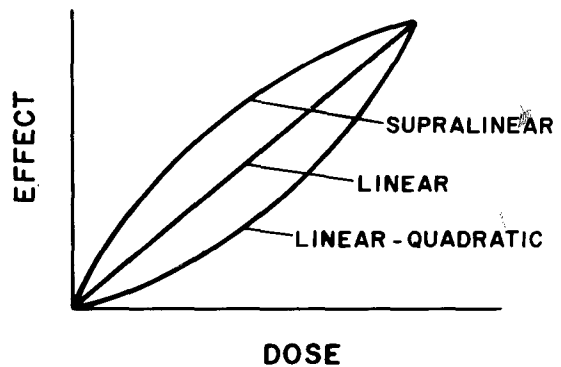


Fig 1. Dose-effect models for biological damage associated with radiation exposure.

the Committee on the Biological Effects of Ionizing Radiation, National Academy of Sciences.⁸ All three models postulate that there is no threshold dose below which radiation-induced injury does not occur; that is, any exposure, no matter how small, is accompanied by a finite increase in risk of a specific biological effect.

In the BEIR III report, cancer was identified as the major risk of radiation exposure. The report presented considerable evidence in support of the linear-quadratic, no-threshold model of radiation-induced cancer. In the linear-quadratic model, the risk increases slowly at low radiation levels; as the dose reaches levels of a few rems or more, the risk increases more rapidly. To minimize risk with this model, a task that requires a certain collective radiation dose† should be divided among several individuals, rather than allocated to only a few, provided that several individuals can function as efficiently as one in completing the task. This approach not only would reduce the risk to any one individual, but also would decrease the adverse effects of the task on the group as a whole. For example, according to the linear-quadratic model, a task that requires a collective dose of 10 person-rems would have less impact on the overall health and well-being of a group of individuals if it were divided among 100 persons, with each person receiving 0.1 rem, than if it were confined to two persons, with each receiving 5 rems, even though

†The collective dose to a group of individuals is the sum of the doses received by all members of the group. The unit of collective dose is person-rems.

either division of labor would satisfy the maximum permissible dose limitation of 5 rem/yr.‡

With the linear dose-effect model, the biological effect is assumed to increase in a straight line (ie, linear) fashion with respect to radiation dose. With this model, the societal risk of task allocation is unaffected by the number of individuals sharing the task, provided that the collective dose remains unchanged. In the example above, no difference in societal impact of the radiation exposure would be experienced irrespective of whether the task was divided among 100 individuals or shared by only two persons. The linear model has been adopted by the ICRP for purposes of prospective radiation protection because it is more conservative (ie, it yields a higher estimate of risk at any given dose) than the linear-quadratic model.

Although not recommended by any recognized advisory group on radiation protection, the supralinear dose-effect model has been proposed by some individuals as the preferred way to predict the biological consequences of exposure to radiation. According to this model, the bioeffects of radiation exposure increase dramatically in the very low-dose region of exposure, then more gradually as the dose reaches more substantial levels. With the supralinear model, a task requiring a certain collective dose would have an increasing societal impact as the number of individuals sharing the task is increased. Under these circumstances, the example described above would have less societal impact if it were confined to two individuals rather than distributed among 100 persons.

Very few experts place much credence in the supralinear model of radiation-induced injury; most of the controversy over the dose-effect models is between proponents of the linear model and supporters of the linear-quadratic model. Since the linear model provides a more conservative estimate of radiation-induced injury at low doses of radiation, a strong case can be made that it should be adopted for purposes of ALARA; it also is the model that yields the easiest ALARA analysis. In the remainder of this article, the

linear model is used to describe an approach to implementation of ALARA in the clinical environment.

AN OPERATIONAL PLAN FOR ALARA

In principle, all individual and collective exposures to radiation are subject to ALARA, no matter how small the exposures may be. In practice, it frequently is impractical to analyze all exposures in a work environment according to ALARA principles, because the effort and expense involved would exceed the value of any expected benefit. Instead, upper and lower boundaries should be established for both individual and collective exposures. These boundaries are identified as "action levels" and "inaction levels" because they stimulate a certain action (or inaction) when they are exceeded (or not exceeded). The terminology of action and inaction levels has been used in the past by the ICRP and has been proposed in draft form by a task group of the NCRP.⁹

Individual action levels (IAL) and individual inaction levels (IIL) can be established by examining the distribution of doses over the population of exposed individuals. Shown in Fig 2 is the cumulative fraction of individuals, and the cumulative fraction of collective dose, plotted as a function of dose. At the upper end of the dose scale, the recommended upper limit of individual dose, termed the maximum permissible dose, is identified as D_{lim} . Very few individuals whose dose exceeds D_{lim} are in compliance with acceptable practices of radiation safety, and their work-

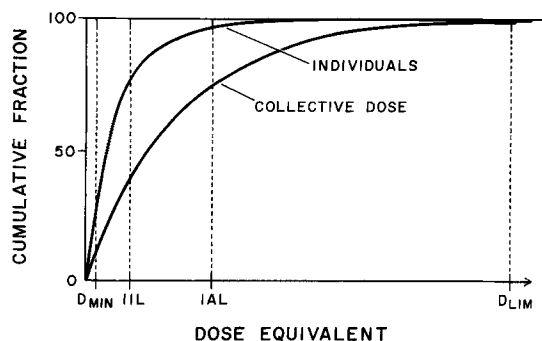


Fig 2. Cumulative fraction of individuals and cumulative fraction of collective dose as a function of dose equivalent.

‡This hypothetical example would not meet the requirements of some advisory and regulatory agencies that specify quarterly, as well as annual, limits on radiation exposure.

ing conditions must be altered independently of any consideration of ALARA principles.

At the opposite end of the dose scale, but above zero exposure, is a level denoted as D_{\min} . This limiting dose is referred to as a "de minimus" level.[§] Individuals receiving doses below this level do not warrant any consideration in terms of ALARA, even though their exposures contribute to the collective dose; their doses are so low that any attempt to reduce them further would not be worth the effort. In many institutions, the de minimus level for external exposure is set operationally as the minimum dose detectable by a personnel monitor (typically 10 mrem); any effort to reduce doses below this level would not yield recognizable results and is not considered worthwhile.^{||}

In some institutions, there may be cost-benefit reasons for raising the de minimus value above the level detectable by personnel monitors. If a higher setting is contemplated, agencies responsible for regulating radiation exposures should be consulted to ensure that there are not legal or institutional policies that govern the de minimus level. In the example presented in Fig 2, about 40% of all workers receive radiation doses below the de minimus level.

Between D_{\lim} and D_{\min} , individual action and inaction levels can be established. The IAL is a level of individual exposure which, if exceeded, automatically triggers a response according to ALARA principles. The IAL is not a dose limitation; ALARA analysis may reveal that the individual exposure is entirely justified. On the other hand, the analysis may suggest that the exposure can be reduced to a reasonably achievable level without compromising the benefits of radiation use and without excessive cost or significantly increased exposures to other individuals. In any institution, a focusing of dose reduction efforts toward those individuals exceeding the IAL often yields the greatest gain for a prescribed level of effort and cost.

Each institution must set its own IAL, depend-

ing upon its exposure history and its philosophy of radiation protection. As a general guideline, the IAL should be greater than the average dose to individuals, but not so high that it is exceeded only in the rarest of instances. Over several review periods, a few percent of the workers would be expected to exceed the IAL. In Fig 2, the IAL is set at a level that is exceeded by approximately 5% of all exposed workers; however, these individuals contribute about 50% of the collective dose of the workers. Obviously, a program to reduce the exposures of the few workers who exceed the IAL would have a significant impact on collective dose.

The individual inaction level (IIL) is defined as the level of individual exposure below which no ALARA activity is warranted. Although exposures below this level could possibly be reduced even further, such reductions imposed on selected individuals according to ALARA principles would have little effect on the collective dose, and probably are not justified economically.

The region between the IIL and IAL encompasses individuals whose exposures may or may not be subject to ALARA analysis, depending on the philosophy and resources of the institution. Persons whose work habits result in exposures consistently within this region probably should be examined from the viewpoint of ALARA. On the other hand, individuals whose exposures fall only occasionally between the IAL and IIL usually are not influenced by ALARA action.

Action levels based on individual exposures are not sufficient to describe the adequacy of

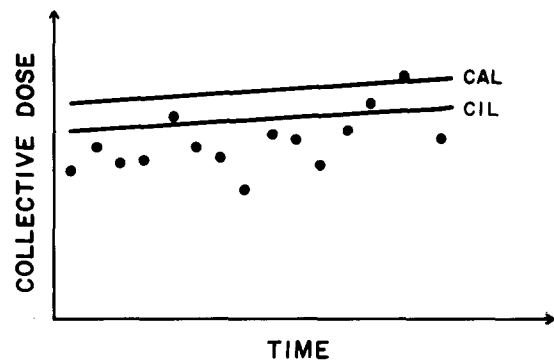


Fig 3. Representative graph of collective dose as a function of time. A collective action level (CAL) and a collective inaction level (CIL) are included.

[§]In its legal interpretation, de minimus is described by the expression "The law does not concern itself with trifles."

^{||}In institutions where significant exposure may result from internally deposited radionuclides, de minimus and other radiation levels should encompass both external and internal exposure.

radiation protection of an institution as a whole. The collective dose to all exposed individuals must also be considered; from a societal point of view, in fact, collective dose determines the overall impact of the radiation exposures on society. To address this issue, an institution should monitor the collective dose contributed by all of its employees over a period of time, as illustrated in Fig 3. Once these data have been compiled, a collective action level (CAL) and a collective inaction level (CIL) can be established, with consideration of trends in the data and allowance for precision of the collective dose data. If during

a subsequent time interval the CAL is exceeded (even if no IAL has been exceeded), then actions should be initiated to reduce the collective dose according to ALARA principles. If during a time interval the CIL is not exceeded, then no further considerations need be taken of possible actions to reduce the collective dose, and attention should be focused on individual exposures and individual action levels. A collective dose between the CAL and the CIL may or may not stimulate ALARA activity, depending on the institution's policies and resources. In larger institutions, it usually is necessary to monitor the

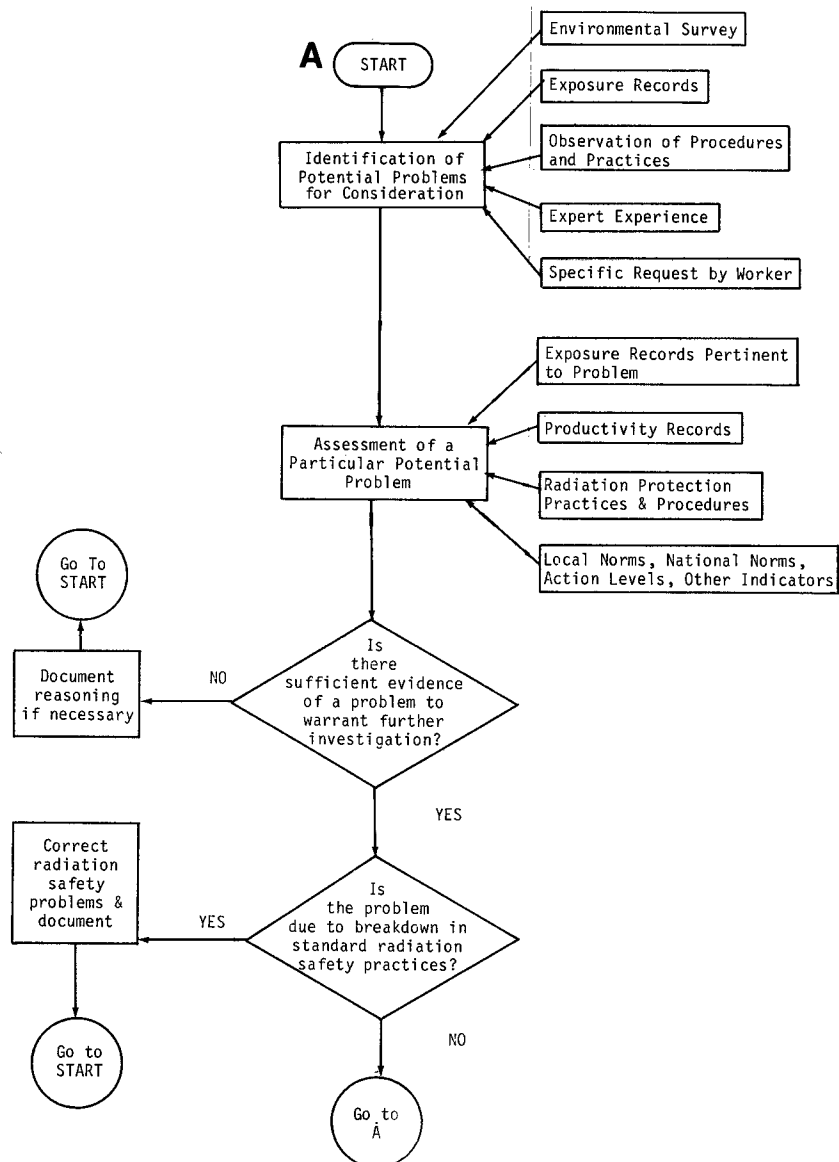


Fig 4. (A and B) Flow chart of ALARA (ORP) in the healing arts. (From a draft report of the Task Group III of Scientific Committee 46 of the National Council on Radiation Protection and Measurements; members: F.M. Edwards [chairman], S. Bushong, G. Dalrymple, J. Gibbs, W. Hendee, and J. Keria-kes.)

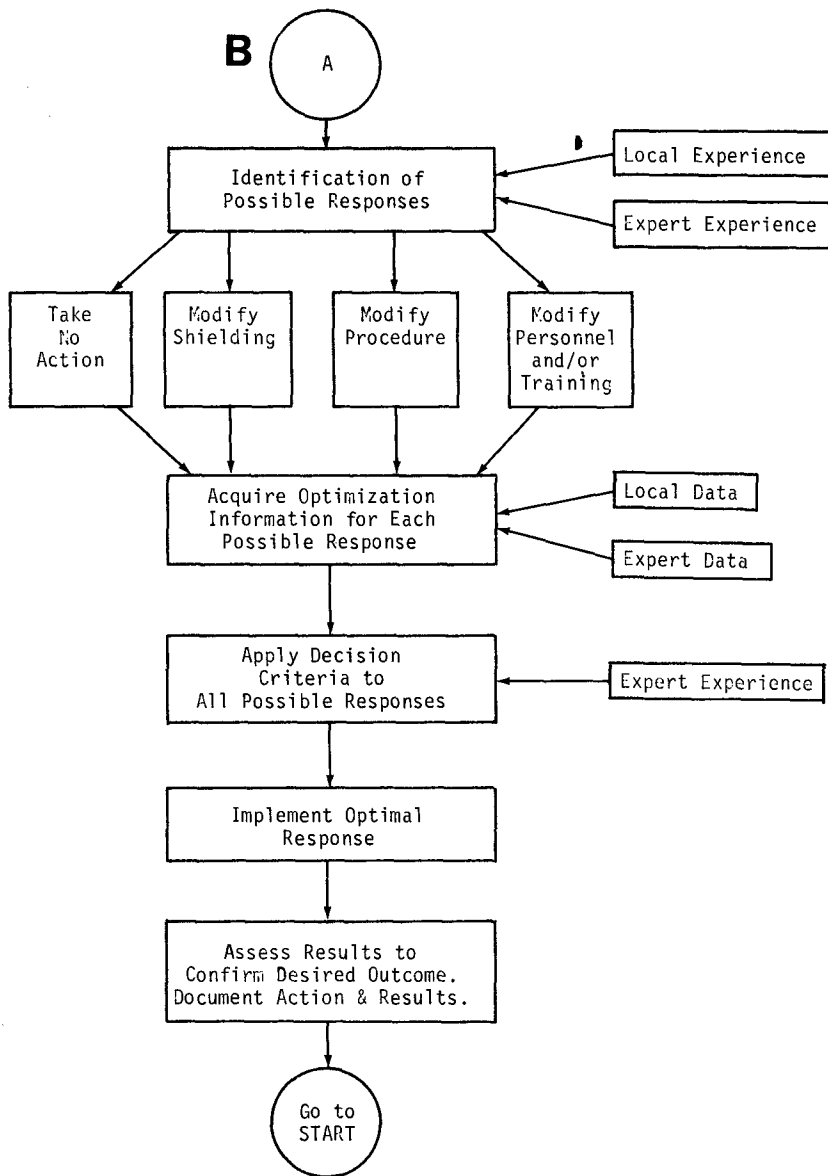


Fig 4. (Cont'd)

collective doses of separate groups of radiation workers and to establish CALs and CILs appropriate for each group. Often, trends in collective doses are related directly to variations in workloads of selected groups of radiation workers; hence, workload data should be compiled in parallel with collective doses as a possible explanation for fluctuations in collective dose.

IMPLEMENTATION OF AN ALARA PROGRAM

An ALARA approach is a supplement to an existing and properly functioning program of radiation protection, and is not a replacement for

such a program. That is, ALARA is a method to optimize the radiation protection program and often requires a large measure of intuition and qualitative value judgment. In many ways, it characterizes the imposition of professional value judgments upon a technically oriented radiation protection program.

The framework for an ALARA program (or an "optimization of radiation protection [ORP] program" as it is termed in the reference containing this illustration) is illustrated in Fig 4. The major components of the framework are: (1) identification of potential problems; (2) assess-

ment of a particular problem; (3) identification of potential responses; (4) acquisition of information for each response; (5) application of ALARA decision process; (6) implementation of response; and (7) evaluation of results. The flow chart in Fig 4 has no end statement, because the ALARA process is envisioned as cyclic.

The initial step in an on-going ALARA program is identification of potential problems most deserving of investigation. As shown in Fig 4A, several sources of data are available for this investigation; however the most fruitful sources of information frequently are personnel monitoring records. A decision chart for review of these records is depicted in Fig 5. Initially, the individual exposures are compared with the IIL and IAL established for the group of exposed individuals; many of the exposures are expected to fall below the IIL, and only a few are anticipated to

exceed the IAL. For exposures below the IIL, no further action is indicated; exposures above the IAL are referred to the "further assessment stage" of the ALARA process. Exposures between the IIL and the IAL are directed one way or the other, depending on the philosophy, resources, and commitment of the institution. Next, the collective dose records are reviewed for the group of exposed individuals. If the collective dose exceeds the CAL, further investigation is indicated; no further action is needed if the collective dose falls below the CIL. Collective doses between the CIL and CAL are distributed one way or the other, depending on the institution's policies and resources.

Once a potential problem has been identified, either from personnel monitoring records or from other sources such as those depicted in Fig 4A, additional data are collected to help characterize

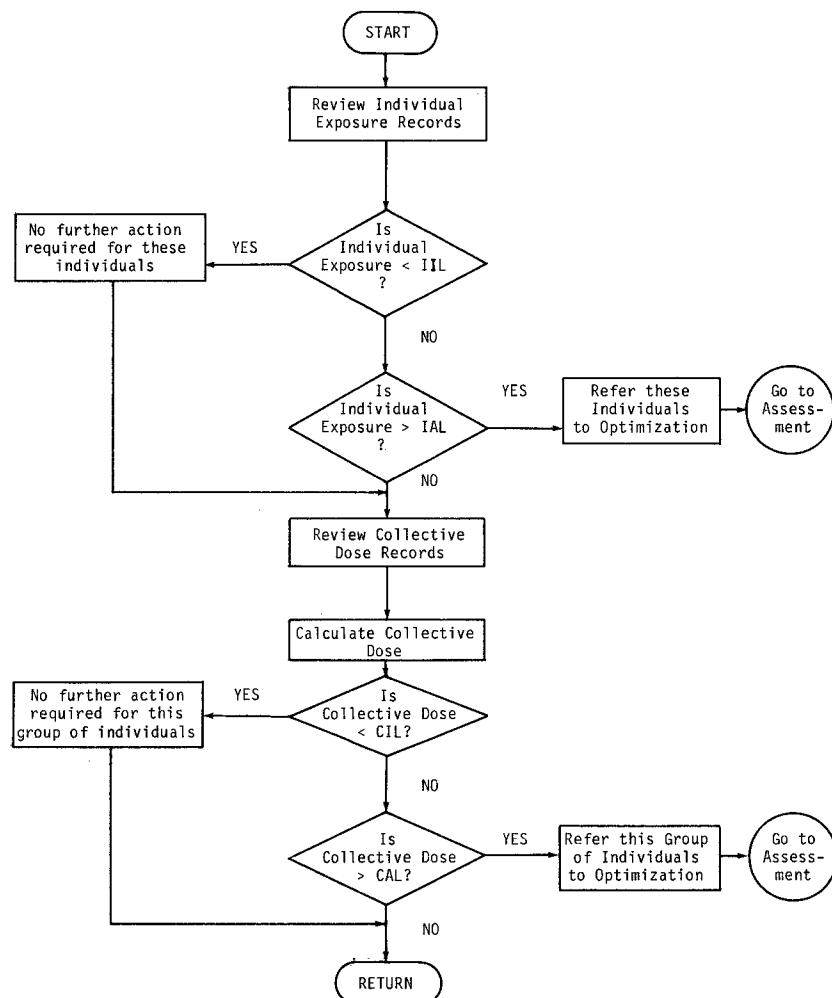


Fig 5. Flow chart of ALARA (ORP) applied to analysis of individual monitoring records.

the nature and extent of the problem. These data may suggest that the problem does not warrant further investigation (eg, an increase in collective dose above the CAL could indicate simply that the number of examinations conducted by the department has increased). On the other hand, the data may reveal that a deficiency exists in the radiation safety program. In this case, the deficiency should be corrected at the earliest opportunity. If neither of these responses addresses the problem appropriately, then further evaluation is needed.

To evaluate a problem further, all possible responses to the problem should be considered. These responses are indicated in Fig 4B as "take no action," "modify shielding," "modify procedure," and "modify personnel or training"; other possible responses can be envisioned for specific problems. "Take no action" is always a possible action since ALARA analysis may indicate that any other response requires a commitment of resources exceeding the capacity of the institution or the benefit to be derived.

If the decision is made to pursue possible responses to the problem, then information must be acquired for each possible response, including the resources required and the potential of the response to solve the problem. It also is necessary to ensure that a particular response does not create other problems such as a compromise in

patient care or the creation of another radiation protection problem. These data are evaluated and a decision is made about which of the possible responses should be implemented.

Once the decision is implemented, a follow-up procedure should be performed to evaluate the effectiveness of the response in addressing the problem. The effectiveness should be documented, and the entire ALARA process should be continued as indicated by the final statement in Fig 4B, "go to start."

An effective program of radiation protection depends not only upon codified recommendations and regulations concerning radiation safety, but also upon the judgment and insight of professionals responsible for radiation safety in the institution. This reliance on professional judgment is a pivotal component in the practice of satisfactory radiation safety, especially when dealing with uncertainties in the extent of risks resulting from exposure to low level radiation, and with uncertainties concerning the protective measures best suited to particular exposure situations. It has been recognized for many years that professional judgment goes far beyond the simple provision of protective measures that satisfy prescribed exposure limits, whether or not the limits are advisory or regulatory in nature. This judgment is the very foundation for the ALARA program described here.

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