Exposure Rates in High-Level-Control Fluoroscopy for Image Enhancement

High-level fluoroscopic boost options that exceed conventional exposure limits are available as a means of reducing quantum mottle during angiography. Federal law does not specify exposure limits for such high-level controls but requires specific means of activation to safeguard against inadvertent use. The American Association of Physicists in Medicine recently recommended that high-level exposure rates not exceed 2.58 mC/kg/min (10 R/min). At six institutions surveyed, maximum exposure rates ranged from 5.42 to 24 mC/kg/min (21–93 R/min). Activation of high-level capability varied from a simple foot switch to a keyed interlock requiring a second operator to engage. There appears to be no industry coherence in high-level control exposure limits as yet, although the Center for Devices and Radiological Health recently initiated an investigatory program.

Index terms: Angiography, 9.1 • Diagnostic radiology, radiation exposure • Fluoroscopy, technology • Radiations, exposure to patients and personnel

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The primary obligation in performing quality control of radiographic and fluoroscopic equipment is to ensure that the equipment complies with all applicable regulations while maximizing image quality and minimizing radiation doses to patients. During routine compliance testing of fluoroscopic equipment without high-level control (HLC), exposure rates in excess of the federally mandated rate of 26 mC/kg/min (10 R/min) are rarely encountered. However, an increasing number of fluoroscopy machines are equipped with an optional HLC that permits the federal limit to be exceeded. An initial investigation of the maximum exposure rate of an HLC machine showed the rate to be four times the conventional limit. Investigations of other HLC machines demonstrated the magnitude of this number to be the norm rather than the exception. Literature and verbal queries revealed a surprising naiveté and paucity of information regarding the potentially high exposure rates. A general desire to increase awareness among the industry and physicians of the potential exposure to patients and staff of radiation during HLC fluoroscopic procedures has led to this investigation.

Conventional exposure limits of image-intensified fluoroscopy are set by the Food and Drug Administration. Title 21 of the Code of Federal Regulations states that

Fluoroscopic Equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens per minute at the point where the center of the useful beam enters the patient except: (i) During recording of fluoroscopic images, or (ii) When an optional high level control is provided. When so provided the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed (1).

Several items are important here. Of greatest significance is that a fluoroscopy mode exists for which there is no maximum exposure limit. Second, although “special means of activation” are required, a large degree of interpretation as to the method of activation is allowed. Third, a subtle difference in semantics exists between “HLC” and “fluoroscopic-image record” modes in that machines equipped with the former have exposure limited in the conventional mode to 1.29 mC/kg/min (5 R/min) rather than 2.58 mC/kg/min (10 R/min). This implies that the fluoroscopist may be obliged to use the HLC option more frequently to achieve an image of adequate quality with such a machine than with one that does not have the HLC option.

Several different terms have been coined by equipment manufacturers to refer to HLC fluoroscopy. These include fluoro boost, high contrast, image enhance, and low noise. HLC fluoroscopy is different from conventional fluoroscopy in that it operates with greater than normal exposure rates provided that certain conditions are met. The higher exposure rate re-

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1 From the Departments of Radiological Sciences (C.H.C.) and Community Safety (S.H.B.), University of California, Los Angeles, BH-254 Center for the Health Sciences (172115), 10833 LeConte Ave, Los Angeles, CA 90024; Department of Radiological Sciences, Olive View - UCLA Medical Center, Sylmar, Calif (N.J.M.); Department of Radiology, University of California, Davis, Sacramento (J.T.B., J.A.S.); and Department of Cardiology, Cedars Sinai Medical Center, Los Angeles (J.S.W). From the 1989 RSNA scientific assembly. Received June 8, 1990; revision requested July 17; revision received October 12; accepted November 19. Address reprint requests to C.H.C.

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Abbreviation: HLC = high-level control.
duces quantum mottle that causes degradation of the fluoroscopic image in an exposure-limited machine. Such degradation is especially significant when a fluoroscopy imaging system is required to image fine anatomic detail through a relatively thick body part. In general, HLC is most commonly found on fluoroscopy equipment used in cardiovascular and digital subtraction angiography, in which oblique projection angles that increase tissue thickness are used and the visualization of tiny blood vessels is required. When performing fluoroscopy of thick body parts, such as in a craniocaudal projection, the automatic brightness control system will drive the milliamperage and kilovolt peak to their maximum values as it attempts to maintain image brightness. In a machine that is limited to the conventional government-mandated exposure limits, maximum kilovolt peak and milliamperage may not be sufficient to overcome loss of image brightness and, depending on design, the machine will attempt to compensate by changing aperture and increasing automatic video gain. In either case, the result is an increase in image noise (2).

Although the Food and Drug Administration does not mandate an exposure limit for HLC fluoroscopy, other, nonregulatory bodies have made recommendations as to what the maximum HLC exposure limit should be. The American Association of Physicists in Medicine states that "it is considered good practice to limit high level control to 2.58 mC/kg-min (10 R/min) unless a specific clinical need has been identified" (3). The County of Los Angeles recommends that the maximum exposure rate not exceed 3.87 mC/kg/min (15 R/min) (Kaufman K, oral communication, 1990).

The preceding guidelines deal with maximum fluoroscopic exposure limits. In addition, the State of California Radiation Control Regulations require that

...for routine fluoroscopy the exposure rate shall be as low as practicable and shall not exceed 5 R/min. This limit shall not apply during magnification procedures or the recording of fluoroscopic images where high exposure rates are required. The useful beam exposure rate shall be measured with a phantom equivalent to 9 inches (22.9 cm) of water or 7/8 inches (20 cm) of lucite (4).

In our survey, several machines were examined for routine fluoroscopic exposure rate with HLC engaged as well as maximum exposure rate.

In addition to the specific regulations and guidelines outlined above, there is a universal responsibility toward radiation protection and the dose-risk relationship. As has been noted by the National Council for Radiation Protection and Measurements, the International Commission on Radiological Protection, and others, it is necessary to always restrict exposure to ionizing radiation to levels that are as low as reasonably achievable (5). The various guidelines and regulations pertaining to HLC fluoroscopy are summarized in Figure 1.

MATERIALS AND METHODS
Data were collected from six academic medical centers in California. To ensure accurate reporting, the contributors were guaranteed anonymity. Each institution was asked to identify (a) machine type, model, and age; (b) HLC appellation; (c) maximum exposure rate as well as the coincident kilovolt peak and milliamperage; (d) method of activation of the HLC fluoroscopy; and (e) frequency and method of use of HLC mode.

The six different institutions that responded provided data on eight different machines from four of the major manufacturers: Philips, Toshiba, Siemens, and OEC-Diasonic. To ensure data consistency, the method for measuring the maximum exposure rate was outlined. The measurement geometry shown in Figure 2 is described in the federal regulations (1). The ion chamber was placed 30 cm from the image intensifier. The automatic exposure control was driven to maximum technique by blocking the face of the image intensifier with lead. It was emphasized that it is often necessary to use lead with a thickness of 6.4 mm (quarter inch) or more to completely drive the technique to maximum on an HLC fluoroscopy unit. The lead was placed as far as possible from the probe so as to minimize contribution to the exposure measurement from backscatter. For those machines with the capability to vary source-image distance, the minimum source-image distance was used.

Three machines were also tested for rate of HLC exposure for a patient of average size in all image-intensifier field sizes (magnification modes). The measurement geometry was identical other than the lead, which was replaced with a patient phantom made of 20 cm (7/8 inches) of Lucite (polymerized methyl acrylate) as is described in the California Radiation Control Regulations (4).

RESULTS
Survey results are shown in Figure 3. Of all the units tested, the maximum reported outputs of radiation during the HLC fluoroscopic proce-
dure varied from a low of 5.42 mC/kg/min (21 R/min) to a high of 24 mC/kg/min (93 R/min). The mean of the exposure rates among the eight machines tested was 12.56 mC/kg/min (48.7 R/min), more than five times the limit recommended by the American Association of Physicians in Medicine. Machines of different models from one manufacturer had exposure rates that varied by 42%, and two machines of the same model from another manufacturer varied by 16%.

The preceding results involve maximum HLC fluoroscopic exposures only. These are the exposures that the machine is capable of producing in extreme situations. To make such high values necessary would require a very large patient or an extreme projection angle, or both. It is informative to look at the values of radiation exposure during a HLC fluoroscopic procedure in an average-sized patient.

Figure 4 shows that the exposure to an average-sized patient increased by 2.3–6.6 times when HLC was activated. Among the machines tested, the highest exposure rate for an average-sized patient in a simulated posteroanterior projection with HLC fluoroscopy engaged was 5.50 mC/kg/min (21.3 R/min), more than four times the exposure rate the State of California mandates as the limit for an average-sized patient in the mode of least magnification.

The degree of difficulty of engaging the HLC also varied widely from machine to machine. As is noted above, for HLC the Food and Drug Administration requires only that there be "continuous manual activation" and a "continuous audible signal" (1). The survey demonstrated that this regulation can be interpreted in many different ways, which are summarized in the Table. In the simplest case, in which normal fluoroscopy is activated by stepping halfway down on a two-position foot switch, HLC could be activated by pressing all the way down. HLC was automatically terminated after 30 seconds. In the most extreme example, initiation of HLC required two people; while the physician in the room depressed the foot switch, another person in the control booth had to turn a key and simultaneously push and hold a button. If any of the three switches was opened, HLC mode was interrupted. In both cases compliance with regulation was met, as there was continuous manual activation. However, it is clear that there is a large disparity between the ways that this regulation was interpreted. All the machines that were investigated invoke a continuous audible tone to warn that HLC is activated, as required by the Food and Drug Administration.

In the survey, we also asked each institution to indicate how frequently the HLC fluoroscopy mode was used. In all cases it was reported that the HLC capability was used less than 5% of the time, and in two cases the HLC capability had been deliberately disabled. In nearly all cases, the HLC mode was used only during percutaneous transluminal coronary angioplasty procedures.

### DISCUSSION

The purpose of the survey was to investigate a technique of radiography that is apparently being used without full cognizance of the potential delivery rate of radiation doses to patients. The survey results were important not only in the high exposure values that were seen, but also in the large variance of the values. It appears that not only is there no adherence to recommended exposure limits but that no industry standard exists, even for a given model of machine. In all cases, the equipment was operated legally but the exposure levels achieved were significant. Follow-up inquiries made to manufacturers suggest that some machines may have been modified to achieve the high exposure levels found in this study. However, in one instance operating parameters were demonstrated to be greater than that which were claimed possible by the manufacturer.

The survey also demonstrated a lack of congruency in the method of activation of the HLC. The intent of the regulation is clearly to make the operator aware that the HLC is engaged, yet the methods of activation ranged from the trivial to one requiring a concerted
effort by two operators.

The Center for Devices and Radiological Health has recently announced its intention to investigate HLC fluoroscopy as an "aspect of fluoroscopic system performance that was not addressed by the radiation safety performance standards for diagnostic x-ray systems" (6). The physician's ultimate question for more diagnostic information in a fluoroscopic image may justify the present open-ended HLC fluoroscopy regulation. However, this quest should be pursued with a full understanding of the consequent exposure to patients. The questions raised by this study are:

1. If there are no governmental regulations regarding the limits of HLC fluoroscopy exposure, should there be any congruency as to how the HLC exposure limits are set?

2. Should exposure limits be set by the physician, the medical physicist, the manufacturer, or all three? Currently, the exposure levels are typically set by the manufacturer or, in practice, by the installation or service engineer. It would be up to the institution and the physician to mandate ceiling levels or to seek the services of a medical physicist to do so. Unofficial conversations with manufacturers' equipment specialists confirm that the usual course of action by the field engineer is to set the milliampere to a specified limit, and the resultant exposure rate is incidental. In fact, the exposure rate may not even be measured, as it is not regulated by the government. After all, the purpose of HLC fluoroscopy is to reduce quantum mottle and the limiting factor is not one of regulation but of machine capabilities.

3. How do the methods of engaging HLC fluoroscopy satisfy the intent of the law? Should it be easy to temporarily increase image quality or should it be extremely difficult to significantly increase patient dose? The latter choice is epitomized by the two-person method of engagement, which is akin to launching a missile. The two-person system ensures an extra measure of radiation protection in that the radiographer must enlist the cooperation of a physician who must consciously activate and maintain the HLC for the duration of the boosted exposure. Advances in design of image intensifiers and in video enhancement allow better image quality at lower dose rates than was previously achievable. However, in specialized applications such as coronary angiography, in which oblique exposure angles are often used, image quality is ultimately limited by quantum mottle and can be improved only by an increase in exposure rate.

4. Should machines with HLC capability be restricted to 1.29 mC/kg/min (5 R/min) maximum in the normal mode? Does such a restriction protect the patient from excessive exposure or merely force the physician to use the HLC mode more frequently? An exposure rate of 1.29 mC/kg/min (5 R/min) may not be enough to provide an adequate image for a large patient or an oblique projection angle, and HLC can be used to overcome this. However, as is seen in the comparison of routine fluoroscopy exposures, evoking the HLC could increase the exposure rate on the order of four and a half times, or twice as much as the conventional ceiling of 2.58 mC/kg/min (10 R/min) would permit. In Figure 4, it is shown that the exposure rate is increased by at least two times for an average-sized patient by invoking the HLC (usually accomplished by increasing the milliampere by a given factor). Rather than having the exposure rate increased by a manufacturer's set amount, the physician ideally should have incremental control over the milliampere. Incremental control would allow the physician to adjust exposure over the normal limit to a level appropriate to the derived diagnostic benefit. Limiting the normal mode of a machine with HLC capability may actually result in greater exposure to patients, as HLC would be used more often in such a machine than in one with a limit of 2.58 mC/kg/min (10 R/min) in the normal mode.

5. Last, should the vendor be obligated to clearly document the actual maximum exposure rate for the user? Because of the high values involved, it is crucial that the exposure rate be periodically monitored and the physician informed of the rate. Reading the kilovoltage peak and milliampere is not enough, as actual exposure depends on generator type, tube type, filtration, and also source-image distance, which is variable on many of the machines. It is difficult to determine what image quality is necessary to perform a procedure or make a diagnosis. Improvements in image quality that are achieved at the cost of increased radiation exposure may be completely reasonable for critically ill patients, and a superior image might decrease overall fluoroscopy time. We recommend that the Center for Devices and Radiological Health address all of the above issues in their examination of HLC fluoroscopy.

To do so requires further research into the risk-versus-benefit scenario of using HLC. The point at which improvement in image quality no longer justifies the increasing amounts of ionizing radiation used must be assessed. What sort of filtration is being used in the fluoroscopy tube? Small differences in the amount of filtration could dramatically change the exposure magnitude. Is there a point of diminishing return at which increasing radiation exposure does not significantly improve the image due to factors like excessive scatter? How much resolution is necessary for the type of dynamic work that is being done?

Moreover, significant, what is an acceptable exposure level for the patient? Although high exposures are not being delivered to the entire body, the potential to administer doses of hundreds or perhaps thousands of centigrays to large areas of the mediastinum exists because of the relatively long fluoroscopy time required for angioplasty procedures. For example, referring to Figure 4, it is seen that the average rate of exposure to a 20-cm (7 1/4 inches) standard Lucite phantom subjected to activation of the HLC is 5.50 mC/kg/min (21.3 R/min). To put this in perspective, 9 minutes of fluoroscopy at this level is equivalent to a single-fraction therapy dose used to treat basal cell carcinoma (7).

Our investigation into HLC fluoroscopy indicates that exposure rates, equipment function, and regulations are inconsistent. Modern fluoroscopy equipment provides an unprecedented capability for exposure delivery that is used to improve image quality under special circumstances. Provisions exist in the radiation control regulations to allow this. However, as is often the case, revision of regulations lags behind technological advances as generators become more efficient and tubes increase in heat-loading capability. All of this must be discussed and understood in an effort to deliver patient doses as low as reasonably achievable.

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