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Records Series Title	R & D Administration Files of Igor Blake, Administrator, Life Sciences Division
Accession No.	434-90-0375
File Code No.	19-18-10
Carton No.	2 of 5
Folder No.	Folder: Occupational Health 1975
Notes	ISAH (1) Operational Safety Procedures
Found at	Richard Longman
Date	1988

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- can't find what
ISAH means.

STATUS VERIFIED UNCLASSIFIED	
<i>[Signature]</i>	12-7-87
Patricia M. Bodin	Date
James W. Criswell	

LAWRENCE
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ORY

Administrative - Operational
Safety
Procedures

October 4, 1988

IN STRICT CONFIDENCE

MEMORANDUM

TO: Ruth M. Larimer
Chair, ad hoc ISAH Review Committee

FROM: Ralph H. Thomas
Division Director, Occupational Health

SUBJECT: Operational Safety Procedure (OSP) for ISAH

Three issues arose at the last Safety Review Committee meeting concerning ISAH:

- Whether an Operational Safety Procedure (OSP) is the appropriate document for ISAH;
- Whether the preparation of an Operational Safety Procedure for ISAH could have serious legal implications for the Laboratory; and
- Whether all aspects of patient (and staff) safety were addressed by the Human Use Committee.

I have reviewed the guidelines for the preparation of OSPs recently approved by the Safety Review Committee and spoken with Dr. Stauffer (Chair, Human Use Committee).

The broad intent of an Operational Safety Procedure is to ensure that "research projects are evaluated for hazard potential and that safety controls are specified and implemented". The responsibility for carrying out this hazards evaluation lies with the Division Director(s). Although it is open to some discussion whether the therapy programs of the Research Medicine Division are research programs we should keep in the forefront of our minds that the principal issue is that the Laboratory requires a safety review of all programs and the responsible Division must consider the preparation of an OSP for all LBL operations that entail the possibility of one or more of the following:

- serious personal injury or death,
- significant adverse environmental consequences,
- substantial equipment or facility damage, or
- significant disruptions to the program.

It is clear that ISAH satisfies one or more of these criteria and that an OSP would be an appropriate means of satisfying the Laboratory's requirement of documenting that a hazards evaluation has been performed. AFRD is already of the opinion that an OSP or equivalent is needed for ISAH.

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DOCUMENT SOURCE	
Lawrence Berkeley Laboratory Archives and Records Office	
Records Series Title	RMD Administration Files of Lyman
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Accession No.	434-90-0375
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With respect to the second item: Dr. Lyman of the Research Medicine Division (RMD) has raised legal questions - particularly the impact of the preparation of an OSP on patient consent. This is an important matter and I believe it should be referred to Laboratory Counsel for a determination.

On the third item: Dr. Stauffer has told me that the Human Use Committee is primarily interested in ensuring adequate safeguards for the patient subjected to research protocols. Staff Safety or program disruption are not considered. The Human Use Committee does not have adequate expertise to carry out in-depth studies of patient safety for complex equipment such as ISAH, and in my opinion, should not be expected to carry out a hazards evaluation on equipment and in patient protocols. It is the responsibility of the program Division Director(s) to ensure that properly documented hazards evaluations are performed. The Human Use Committee should have access to the hazards evaluation documents (normally an OSP). I would recommend further discussion with Dr. Stauffer and the Human Use Committee on this matter.

Summary

- It is the intent of Laboratory Policy that all projects be evaluated for hazards potential. An effective part of this evaluation is the determination whether or not an Operational Safety Procedure must be prepared. The Division Director(s) has/have the responsibility for overseeing that the evaluation is made. (In this case because of dual responsibility, both Directors of AFRD and RMD should concur.)
- ISAH is a candidate for an OSP. The preparation of an OSP would be the simplest means of fulfilling Laboratory requirements.
- The Human Use Committee's review of research protocols is neither broad nor deep enough to satisfy Laboratory requirements for a hazards evaluation.
- Legal questions posed by the Research Medicine Division concerning OSP's should be referred to Laboratory Counsel.
- Should it be determined by the Directors of the Accelerator Fusion & Research Division and the Research Medicine Division that an Operational Safety Procedure is not the appropriate document for ISAH it is my opinion that it will be necessary for an alternative document to be prepared, the context and form of which must be approved by the Safety Review Committee.

RHT:sk

cc: R. Muller
G. Behrsing
K. Berkner
J. Lyman
J. Young

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