


<b>INDUSTRY RELATIONS POLICY</b>	<b>PENNSTATE HERSHEY</b>  Milton S. Hershey Medical Center
<b>Hershey Medical Center – Hospital Administrative Manual</b>	<b>Policy Number: A-89 HAM</b>
<b>Replaces: NEW</b>	<b>Effective: November, 2008</b>
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## **PURPOSE**

To establish guidelines for interactions between industry representatives and PSHMC employees and trainees.

## **INTRODUCTION:**

The relationship between the Penn State Hershey Medical Center (PSHMC) and the pharmaceutical and device industries (INDUSTRY) is complex and multifaceted. Our organization is committed to having responsible interactions with industry representatives in ways that further the core missions of PSHMC. This document outlines a framework for such interactions, contextualized within the organizational mission and values<sup>1</sup>.

Because Penn State Hershey Medical Center is committed to delivering the highest quality medical care with the highest levels of integrity and professionalism, physicians and staff are committed to avoid real or perceived conflicts of interest that would compromise our integrity, undermine the public trust, and/or affect medical decisions or judgments. With the growing awareness that the marketing practices of industry influence medical practice and patient care, the following observations and principles inform the PSHMC Industry Relations policy:

1. The primary obligation of health care professionals is to act in the best interests of their patients.
2. As such, PSHMC employees, trainees, students, and volunteers should identify and eliminate activities that undermine the performance of this primary obligation.
3. Academic medical centers have an obligation to establish policies that promote professional behaviors and further the best interests of patients.
4. There is a growing body of social science literature demonstrating that industry's interactions with physicians affect professional behaviors (1-3).
5. Although many physicians do not believe they are personally susceptible to such influences (4), the evidence shows that physicians are collectively influenced. Physicians' interactions with industry correlate, for example, with their prescribing newer, more costly drugs—whether or not these newer products offer substantial benefit over existing therapies (5, 6).
6. Existing policies do not sufficiently address the potential conflicts of interest that arise from industry's interactions with physicians' (7).

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<sup>1</sup> <http://infont.hmc.psu.edu/facts/summit/vision.htm>

7. Failure to address these concerns threatens to undermine public trust in the medical profession (8, 9).
8. Leaders within academic medicine have called for greater self-regulation of industry interactions at academic medical centers (7), many U.S. academic medical centers have recently developed guidelines restricting such interactions, and the AAMC has issued Industry Relations recommendations (10).
9. To promote and enhance the trust of patients and others served by PSHMC, and to support the institutional values of honesty, integrity and excellence, PSHMC's Industry Relations policy aims to establish whether particular kinds of interactions with industry are **permitted, discouraged, or prohibited**. The goal is to eliminate conflicts of interest when possible, and reduce and/or manage those that remain.

#### **SCOPE:**

This policy is intended to cover interactions that involve marketing of products, on-site training, and/or education. It applies to all faculty, staff, residents, students and trainees at PSHMC. Excluded from this policy are interactions with industry concerning clinical or basic science research —with the one exception of academic authorship (discussed below, under Speakers Bureaus and Academic Activities).

#### **CROSS REFERENCES:**

While this policy addresses many aspects of industry interaction, it supplements other policies and practices, including:

<a href="#">RA20</a>	Individual Conflict of Interest
<a href="#">A60 HAM</a>	Conflict of Interest Policy
<a href="#">RA05</a>	Research Conflict of Interest
<a href="#">HR80</a>	Private Consulting Practice
<a href="#">A20 HAM</a>	Code of Ethical Behavior
<a href="#">A65 HAM</a>	Vendor Visitation/Solicitation to Clinical/Non-Clinical Work Areas

#### **DEFINITIONS:**

INDUSTRY refers to any pharmaceutical, biotech, medical device, supplies, and/or hospital and research equipment and supplies company or entity.

GIFTS include, but are not limited to, the following:

- Cash, loans, gift certificates, discounts, entertainment
- Food or beverage (or vouchers for such items)
- Trinkets (e.g., pens, notepads, clocks, and other office items)
- Professional accoutrements (e.g., calipers, penlights, I.D. holders)
- Books, manuals, models, and other such educational items
- Services
- Drug samples (when given to PSHMC employees or trainees)

CONFLICTS OF INTEREST: Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. In terms of industry influences, financial conflicts of

interest occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain (7).

**MANAGEMENT OF CONFLICT OF INTEREST:** In some cases, appropriate management of a conflict of interest will mean eliminating the conflict (e.g., outside relationship or activity) altogether. In other cases, appropriate management may involve careful monitoring and reporting of the activities, allowing important activities to go forward with assurances that the integrity of the individual and institution will be protected. These situations will require careful review, monitoring, and documentation (11).

## **SPECIFIC ACTIVITIES:**

### **I. Gifts and Compensation**

Gifts from industry are a form of marketing intended to create a relationship that can influence decision-making. Though it is hard to know how much any particular decision is influenced by receipt of a gift, the practice has been shown to influence physicians' behavior in the aggregate (3).

- A. As such, industry representatives are prohibited from giving any form of gift to physicians and other faculty, staff, students, and trainees on the PSHMC campus.
- B. Physicians and other faculty, staff, students, and trainees may not accept any gifts from industry representatives on the PSHMC campus, including meals and gifts of trivial material value.
- C. Moving an interaction with industry representatives to an off-campus location in order to avoid these restrictions would be in violation of this policy.
- D. When attending off campus meetings, conferences, etc., faculty, staff, students, and trainees are discouraged from accepting gifts (which includes meals) from industry representatives.
- E. Gifts containing industry brands and/or logos such as clocks, posters, post-it pads, etc. are marketing tools, and should not be displayed in clinical and teaching areas. Anatomic models or charts that are deemed critical for patient education are permitted, but non-branded versions are preferred.
- F. Employees and trainees may not accept any form of compensation for listening to a promotional presentation ("detailing") by an industry representative.
- G. Employees and trainees may not accept any form of compensation or rebate for prescribing or changing a patient's prescription.
- H. Even if a gift is covered by an exception, staff may not accept a gift if it would undermine the appearance of PSHMC's integrity.<sup>2</sup>

### **II. Food**

- A. Industry-sponsored meals in the workplace are not permissible on campus, with the

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<sup>2</sup> Gifts from Vendors/Business Associates, A73 HAM

exception of food provided in connection with Accreditation Council for Medical Education (ACCME) accredited programming and in compliance with ACCME guidelines (12).

### **III. Site Access by Pharmaceutical Representatives**

- A. Access to physicians and providers is by faculty invitation and appointment only. Interactions with trainees, students, or staff without faculty invitation and oversight are not permissible. Interactions are restricted to non-public and non-patient care areas. Pharmaceutical representatives wishing access to the PSHMC campus must register with the Purchasing Department and agree to abide by PSHMC policy A65 HAM<sup>3</sup> prior to engaging in any interaction with PSHMC physicians, providers or trainees.
- B. An appointment with one individual or group does not grant permission to meet with other individuals or groups, and upon completion of an appointment, industry representatives must promptly leave the area.
- C. Pharmaceutical representatives who wish to provide educational information on their products may do so by invitation only, in faculty-supervised structured settings that provide the opportunity for interaction and critical evaluation.

### **IV. Site Access by Device Manufacturer Representatives**

- A. Access to physicians and providers is by faculty invitation and appointment only. Interactions with trainees, students, or staff without faculty invitation and oversight are not permissible. Representatives must be appropriately credentialed and adhere to procedures outlined in policy A65 HAM.
- B. Accepted purposes for physician and provider contact with device manufacturer representatives include:
  - Training for new equipment or new procedures with existing equipment
  - Training for a complex procedure requiring technical consultation
  - Product and equipment trials or demonstrations
  - Research and/or field testing of unreleased products or devices
  - Other contacts by approval from the department Chair
- C. Device manufacturer representatives are not permitted to be present during any patient care interaction except under very special circumstances, and then only if there has been prior disclosure to and consent by the patient, and for the purpose of providing in-service training, demonstration, or assistance on devices and equipment.
- D. Additionally, representatives:
  - May not touch patients
  - May not operate any PSHMC equipment or devices, except under extenuating circumstances (e.g. equipment malfunction) or to provide specialized training under the direction of a PSHMC physician
  - May not have access to patient records except with HIPAA-compliant prior

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<sup>3</sup> Vendor Visitation/Solicitation to Clinical/Non-Clinical Work Areas A65 HAM

authorization

**V. Other Contact With Industry Representatives**

- A. Industry representatives may not attend Grand Rounds, Departmental meetings, or other PSHMC gatherings except by invitation.
- B. PSHMC employees and trainees are discouraged from accepting educational materials from Industry representatives. However, upon request, representatives may provide such materials provided they are: 1) peer-reviewed (e.g., journal articles, The Medical Letter, Prescriber's Letter, Cochrane reviews, etc.), and 2) for educational purposes.
- C. Interactions with industry representatives during non-work hours are permitted as long as they are not in violation with other aspects of this policy. However, these interactions are to be viewed with caution, since many such interactions involve marketing tactics intended to influence behavior, which would violate the spirit of this policy.

**VI. Financial Support for Educational, Training, and/or Professional Activities**

- A. Because Industry support of students and trainees may involve real or perceived conflicts of interest, financial support must be specifically for the purpose of education, training and/or professional activities, and must comply with all of the following provisions:
  - Support is provided to the Department, Institute, or Division, not to individual faculty, trainees, or students
  - Support complies with ACCME Standards for Commercial Support whether or not CME credit is awarded (12)
  - Support is documented for record-keeping purposes
  - Support is fully disclosed
  - The recipient is not subject to any implicit or explicit expectation of providing something in return for the support (i.e., no quid pro quo)
  - No materials carrying a product (or company) name or logo is distributed
- B. Financial support to defray travel/lodging/registration costs for PSHMC employees or trainees to attend educational or professional conferences is permissible, provided that:
  - Funds are given as part of an unrestricted educational grant administered by the Department, Institute, or Division
  - Selection of PSHMC employees or trainees for such support is made by the Department, Institute, or Division without input from the industry sponsor
  - There is no contract nor expectation (explicit or implicit) that medical or purchasing decisions will be linked to such support
- C. Payment to attend a lecture or conference qualifies as a gift, and therefore is not permitted. The same holds true for any payment/compensation for time at professional meetings.

## **VII. Speakers Bureaus and Academic Activities**

- A. Serving as a paid presenter on industry speakers' bureaus is discouraged because:
- Such speaking engagements are part and parcel of industry marketing
  - This kind of relationship creates a conflict of interest that may undermine or appear to undermine the impartiality of the speaker as a medical professional
  - Such conflicts are readily avoidable
- B. Should a PSHMC employee or trainee wish to serve as a paid presenter on an industry speakers' bureau:
- He or she must notify the department Chair of the nature and frequency of these activities
  - No reference may be made to the speaker's PSHMC title or affiliation in any promotional material
  - The speaker must make clear in his/her presentation and handouts that their views do not reflect the views or endorsement of PSHMC
  - Payments to the PSHMC employee must not exceed fair market value
- C. Payment from industry representatives to serve as an author for an academic publication undermines the integrity of the scientific process and is prohibited for all PSHMC employees and trainees.
- D. Any PSHMC employee or trainee listed as an author on a manuscript submitted for publication must meet established criteria for authorship as required by major scientific journals. Presentations and publications must not be "ghost-written" by industry or other third-parties.

## **VIII. Consulting with Industry**

It is a priority for PSHMC to promote meaningful, productive relationships with industry in order to further shared values and goals. PSHMC acknowledges the value of permitting academic medical center faculty to interact appropriately with industry. Examples of appropriate interaction include faculty participation on industry boards of directors and scientific advisory boards as well as services provided through professional services agreements and consulting contracts, provided such activities are conducted in full compliance with other policies of the medical center and applicable law, and that compensation reflects the fair market value of the services provided. As such:

- A. PSHMC employees or trainees may serve as consultants, to the extent that such consulting involves legitimate professional activities.
- B. Such activities must be consistent with PSHMC consulting policies<sup>4</sup>, and reimbursement should reflect fair market value.
- C. Participation in activities for marketing purposes such as telephone "interviews," expert panels, or marketing surveys is discouraged.

## **IX. Drug and Product Samples**

The provision of free drug and product samples to patients in need is an important service

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<sup>4</sup> Penn State University Policy HR80 Private Consulting Practice

that is consistent with institutional missions and values. That said, the practice of stocking closets with samples provided by industry representatives raises many issues:

- The samples they provide are typically the newest (and often most expensive) medications or products that may not be first-line treatment for the presenting medical problem
- Patients started on drug samples are often continued on these medications when lower cost alternatives exist (5, 6, 13)
- Physician prescribing habits can be influenced by the use of samples (14)
- Generic or older/cheaper products are typically not provided
- Direct dispensing by physicians bypasses the services that pharmacists typically provide, thereby increasing the chance of dosing and drug interaction errors, and this can compromise patient safety
- Drug samples are more likely to be distributed to the wealthy and insured (15) than to the poor or uninsured

Therefore,

- A. The provision of drug sample closets is discouraged, and samples should be centrally managed and documented to minimize potential problems, while ensuring timely patient access.
- B. Where feasible, this sample repository should include generic as well as name-brand medications.
- C. Drug samples may not be sold to anyone.
- D. Drug samples are for patients and not to be diverted to providers or their families.

## **X. Drug Formularies**

- A. PSHMC faculty who serve on the PSHMC Pharmacy & Therapeutics Committee and/or other committees involved in drug or device purchasing decisions should not have financial conflicts of interest involving industries that may benefit from institutional decisions in which they are involved. Such conflicts of interest include:
  - Direct equity ownership in the company
  - Receiving compensation for position on advisory boards
  - Serving as a paid consultant
  - Serving on an industry speaker's bureau
  - Grants from industry
- B. If real or perceived conflicts are present, they must be disclosed to the institutional Conflicts of Interest Committee, which will decide whether the individual should be disqualified from the committee or barred from specific decisions.<sup>5</sup>

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<sup>5</sup> Conflict of Interest Policy, A60 HAM

**PERSON RESPONSIBLE FOR REVIEW**

Chief Medical Officer  
Administrator, Support Services Integration

**REFERENCES**

Analytical Framework - Attachment A  
Industry Relations Policy Consensus – Attachment B

Reviewed:

Revised:

Hospital Administrative Manual	Policy Number: A-89HAM
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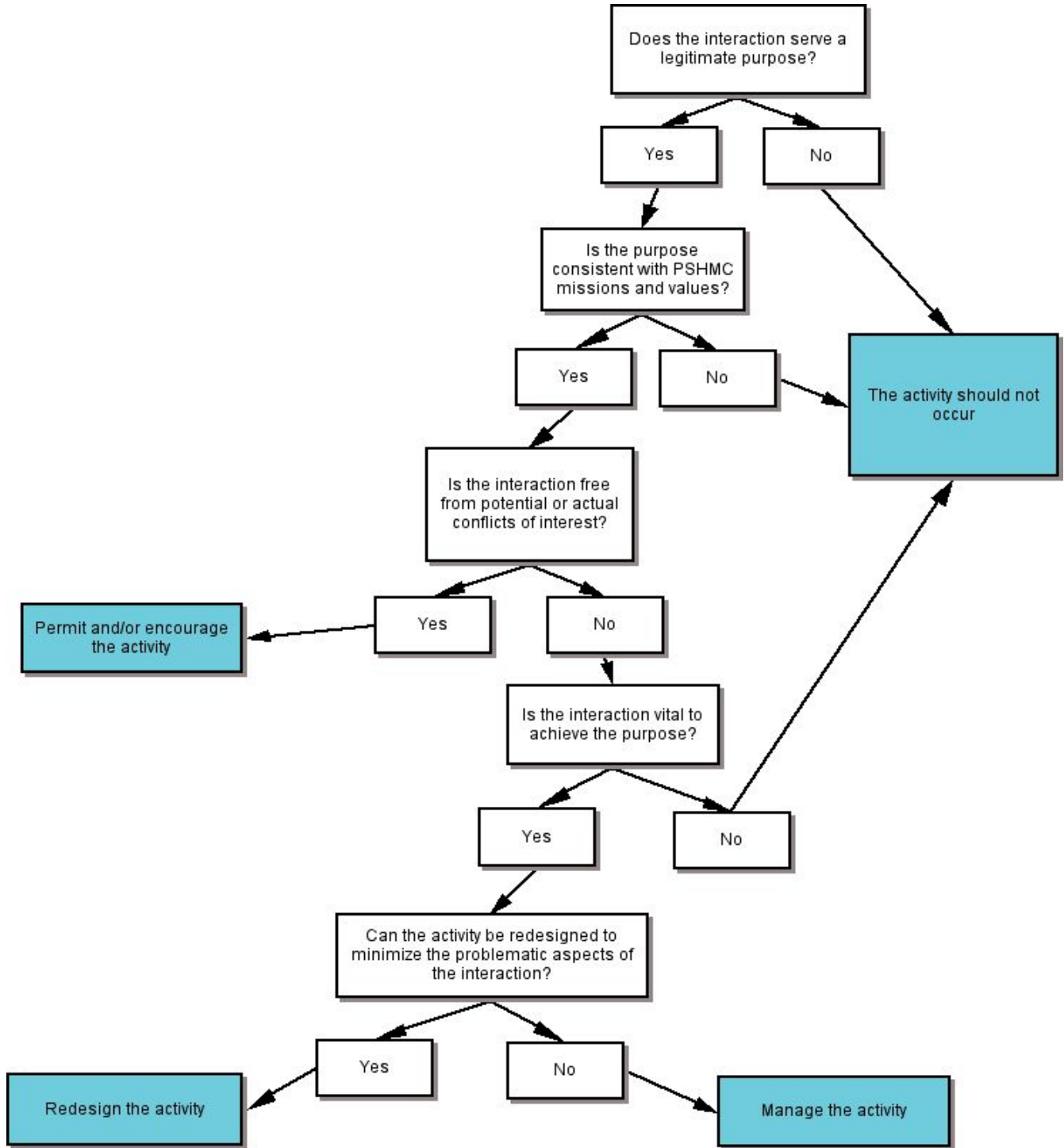
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# Attachment A

## ANALYTIC FRAMEWORK

In determining whether a particular interaction with industry is appropriate, the following analytic framework has been applied.



## Industry Relations Policy Consensus

The following grid represents the collective recommendations of PSHMC Departments and Institutes, in compliance with the 2008 AAMC Task Force on Industry Funding of Medical Education report (1).

<b>Gifts to Individuals<sup>i</sup></b>	Permit	Discourage	Prohibit
On campus			✓
Off campus		✓	
Industry-sponsored meals in the workplace			✓
Industry-branded merchandise			✓
Compensation for listening to detailing			✓
Compensation or rebate for prescribing a particular medication			✓
<b>Site Access by Pharmaceutical Representatives<sup>ii</sup></b>	Permit	Discourage	Prohibit
Employee contact with industry representatives at work	✓		
Employee contact after-hours		✓	
Patient contact			✓
Access to medical records			✓
Attending medical conferences or departmental meetings		✓	
Providing educational materials to employees		✓	
<b>Site Access by Device Representatives<sup>4</sup></b>	Permit	Discourage	Prohibit
In patient care areas	✓		
Patient care interactions	✓		
Access to medical records			✓
<b>Financial Support for Educational, Training, and/or Professional Activities</b>	Permit	Discourage	Prohibit
Support to individuals			✓
Support to Departments or Divisions	✓		
Support to defray travel/lodging/registration	✓		
Payment to attend conference			✓
<b>Speakers Bureaus and Academic Activities</b>	Permit	Discourage	Prohibit
Serving as a paid presenter on industry speakers' bureaus		✓	
Payment from industry representatives to serve as an author on an academic article			✓
Participation in ghost written article			✓
<b>Consulting with Industry</b>	Permit	Discourage	Prohibit
Paid consulting with industry	✓		
Participation in marketing activities (phone interviews, expert panels, surveys, etc.)		✓	
<b>Drug or other Product Samples</b>	Permit	Discourage	Prohibit
Establishing a sample closet		✓	
Diversion of samples by providers for use by self or families			✓
Selling samples to patients			✓

- 1 Refers to any gift, regardless of value
- 2 Moving an interaction with industry representatives to an off-campus location in order to avoid gift restrictions would be in violation of this policy. When attending off campus meetings, conferences, etc., faculty, staff, students, and trainees are discouraged from accepting gifts (which includes meals) from industry representatives.
- 3 With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines
- 4 Unless critical for patient education and otherwise unavailable (e.g. growth charts, anatomic models, etc).
- 5 Must comply with A-65 HAM
- 6 By faculty invitation and appointment only and restricted to non-patient care areas. Interactions with trainees or staff without faculty invitation and oversight are not permissible.
- 7 Must be in compliance with all other aspects of this policy
- 8 By faculty invitation only
- 9 Only upon employee initiation; should be peer-reviewed
- 10 With proper credentialing and by faculty invitation and appointment only
- 11 Representatives are not allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patients, and then only to provide inservice training or assistance on device equipment
- 12 Must be in the form of unrestricted grant; no quid pro quo
- 13 In the form of unrestricted grants to the Department/Institute/Division and not to individuals
- 14 Must be in compliance with HR80, and compensation should not exceed fair market value
- 15 Should be centrally managed

## **Bibliography**

1. Association of American Medical Colleges. Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council. Washington DC; 2008 June 18-19, 2008.

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<sup>i</sup> Refers to any gift, regardless of value

<sup>ii</sup> Must comply with A-65 HAM